IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., Plaintiff, v. APOTEX, INC., LUPIN LIMITED, LAURUS LABS LIMITED, SHILPA MEDICARE LIMITED, SUNSHINE LAKE PHARMA CO., LTD., NATCO PHARMA LIMITED, CIPLA LIMITED, MACLEODS PHARMACEUTICALS LTD., HETERO USA INC., HETERO LABS LIMITED UNIT-V, AND HETERO LABS LIMITED, Defendants.	C.A. No. 20-189 (MN) **JURY TRIAL DEMANDED**

PLAINTIFF GILEAD SCIENCES, INC.'S SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead"), by its undersigned attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendants Apotex, Inc. ("Apotex"), Lupin Limited ("Lupin"), Laurus Labs Limited ("Laurus Labs"), Shilpa Medicare Limited ("Shilpa"), Sunshine Lake Pharma Co., Ltd. ("Sunshine Lake"), Natco Pharma Limited ("Natco"), Cipla Limited ("Cipla"), Macleods Pharmaceuticals Ltd. ("Macleods"), and Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited (collectively, "Hetero"). This action arises out of Defendants' filing of one or more Abbreviated New Drug Applications ("ANDA") with the United States Food and Drug Administration ("FDA").

2. Defendants seek approval to market generic versions of Gilead's products containing tenofovir alafenamide ("TAF"), including VEMLIDY®, DESCOVY®, and ODEFSEY®, prior to the expiration of two or more of U.S. Patent Nos. 7,390,791; 7,803,788; 8,754,065; and 9,296,769 (collectively, the "Patents-In-Suit"). Gilead attaches hereto a true and accurate copy of each of the Patents-In-Suit as Exhibits A-D.

PARTIES

Plaintiff

3. Gilead is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

4. Gilead is a research-based pharmaceutical company that discovers, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for human immunodeficiency virus ("HIV"), hepatitis B virus ("HBV"), hepatitis C virus ("HCV"), liver diseases, serious cardiovascular and respiratory diseases, and cancer. Gilead's portfolio of products includes treatments for HBV and HIV using the drug TAF. Gilead sells TAF-containing pharmaceuticals under the registered trademarks VEMLIDY, DESCOVY, and ODEFSEY in this District and throughout the United States.

Defendant Apotex

5. On information and belief, Apotex is a foreign corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9l 1T9.

6. On information and belief, Apotex, itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

7. On information and belief, Apotex prepared and filed ANDA No. 213867 ("Apotex's VEMLIDY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's VEMLIDY product ("Apotex's VEMLIDY ANDA Product") in the United States, including in this District, if the FDA approves Apotex's VEMLIDY ANDA.

8. On information and belief, Apotex prepared and filed ANDA No. 214053 ("Apotex's DESCOVY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's DESCOVY product ("Apotex's DESCOVY ANDA Product") in the United States, including in this District, if the FDA approves Apotex's DESCOVY ANDA.

9. On information and belief, Apotex prepared and filed ANDA No. 214095 ("Apotex's ODEFSEY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's ODEFSEY product ("Apotex's ODEFSEY ANDA Product") in the United States, including in this District, if the FDA approves Apotex's ODEFSEY ANDA.

Defendant Lupin

10. On information and belief, Lupin is a foreign corporation organized and existing under the laws of India, having its principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai, 400055, India.

11. On information and belief, Lupin, itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

12. On information and belief, Lupin prepared and filed ANDA No. 214226 ("Lupin's

VEMLIDY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's VEMLIDY product ("Lupin's VEMLIDY ANDA Product") in the United States, including in this District, if the FDA approves Lupin's VEMLIDY ANDA.

13. On information and belief, Lupin prepared and filed ANDA No. 213926 ("Lupin's DESCOVY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's DESCOVY product ("Lupin's DESCOVY ANDA Product") in the United States, including in this District, if the FDA approves Lupin's DESCOVY ANDA.

14. On information and belief, Lupin prepared and filed ANDA No. 214227 ("Lupin's ODEFSEY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's ODEFSEY product ("Lupin's ODEFSEY ANDA Product") in the United States, including in this District, if the FDA approves Lupin's ODEFSEY ANDA.

Defendant Laurus Labs

15. On information and belief, Laurus Labs is a foreign corporation organized and existing under the laws of India, having its principal place of business at Serene Chambers, Road No. 7, Banjarahills, Hyderabad, 500 034, India.

16. On information and belief, Laurus Labs itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

17. On information and belief, Laurus Labs prepared and filed ANDA No. 214030 ("Laurus Labs's VEMLIDY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's VEMLIDY product ("Laurus Labs's VEMLIDY ANDA Product") in the United States, including in this District, if the FDA approves Laurus Labs's VEMLIDY ANDA.

18. On information and belief, Laurus Labs prepared and filed ANDA No. 213989 ("Laurus Labs's DESCOVY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's DESCOVY product ("Laurus Labs's DESCOVY ANDA Product") in the United States, including in this District, if the FDA approves Laurus Labs's DESCOVY ANDA.

Defendant Shilpa

19. On information and belief, Shilpa is a foreign corporation organized and existing under the laws of India, having its principal place of business at #12-6-214/A1, Hyberabad Road, Raichur – 584 135, Karnataka, India.

20. On information and belief, Shilpa itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

21. On information and belief, Shilpa prepared and filed ANDA No. 214072 ("Shilpa's VEMLIDY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's VEMLIDY product ("Shilpa's VEMLIDY ANDA Product") in the United States, including in this District, if the FDA approves Shilpa's VEMLIDY ANDA.

Defendant Sunshine Lake

22. On information and belief, Sunshine Lake is a foreign corporation organized and existing under the laws of China, having its principal place of business at Northern Industry Road No. 1, Song Shan Lake Technology Industry Park, Dongguan 52380-8 Guangdong, China.

23. On information and belief, Sunshine Lake itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

24. On information and belief, Sunshine Lake prepared and filed ANDA No. 213845 ("Sunshine Lake's VEMLIDY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's VEMLIDY product ("Sunshine Lake's VEMLIDY ANDA Product") in the United States, including in this District, if the FDA approves Sunshine Lake's VEMLIDY ANDA.

Defendant Natco

25. On information and belief, Natco is a foreign limited liability company organized and existing under the laws of India, having its principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad, 500-034, India.

26. On information and belief, Natco itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

27. On information and belief, Natco prepared and filed ANDA No. 214173 ("Natco's DESCOVY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's DESCOVY product ("Natco's DESCOVY ANDA Product") in the United States, including in this District, if the FDA approves Natco's DESCOVY ANDA.

Defendant Cipla

28. On information and belief, Cipla is organized and existing under the laws of India, having its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

29. On information and belief, Cipla itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

30. On information and belief, Cipla prepared and filed ANDA No. 214059 ("Cipla's DESCOVY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's DESCOVY product ("Cipla's DESCOVY ANDA Product") in the United States, including in this District, if the FDA approves Cipla's DESCOVY ANDA.

31. On information and belief, Cipla prepared and filed ANDA No. 214058 ("Cipla's ODEFSEY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's ODEFSEY product ("Cipla's ODEFSEY ANDA Product") in the United States, including in this District, if the FDA approves Cipla's ODEFSEY ANDA.

Defendant Macleods

32. On information and belief, Macleods is organized and existing under the laws of India, having its principal place of business at Atlanta Arcade, Marol Church Rd., Andheri (East), Mumbai, 400059, India.

33. On information and belief, Macleods itself and through its subsidiaries, affiliates, and agents, manufactures, distributes, and/or imports generic pharmaceutical products for sale and use throughout the United States, including in this District.

34. On information and belief, Macleods prepared and filed ANDA No. 214216 ("Macleods's DESCOVY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's DESCOVY product ("Macleods's DESCOVY ANDA Product") in the United States, including in this District, if the FDA approves Macleods's DESCOVY ANDA.

Defendant Hetero

35. On information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a registered agent for the service of process at W/K Incorporating Services, Inc., 3500 S Dupont Hwy, Dover, Delaware 19901, and its principal

place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854. On information and belief, Hetero USA Inc. is the U.S. Regulatory Agent for Hetero Labs Limited, including Hetero Labs Limited Unit-V.

36. On information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2 Hetero Corporate, Industrial Estates, Sanath Nagar, Hyberabad 500 018, Telengana, India.

37. On information and belief, Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad, Telangana 500018, India. On information and belief, Hetero Labs Limited Unit-V is a division of Hetero Labs Limited.

38. On information and belief, Hetero prepared and filed ANDA No. 214179 ("Hetero's VEMLIDY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's VEMLIDY product ("Hetero's VEMLIDY ANDA Product") in the United States, including in this District, if the FDA approves Hetero's VEMLIDY ANDA.

39. On information and belief, Hetero prepared and filed ANDA No. 211850 ("Hetero's DESCOVY ANDA"), seeking approval to manufacture, import, market, and/or sell a generic version of Gilead's DESCOVY product ("Hetero's DESCOVY ANDA Product") in the United States, including in this District, if the FDA approves Hetero's DESCOVY ANDA.

JURISDICTION AND VENUE

40. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 et seq., including §§ 271(e)(2), 271(a), 271(b), 271(c), 271(g) and 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

41. The Court also has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Plaintiff and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the Patents-In-Suit.

Jurisdiction and Venue for Defendant Apotex

42. This Court has personal jurisdiction over Apotex by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Apotex regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Apotex currently markets and sells over 90 pharmaceutical products throughout the United States, including in Delaware. On information and belief, Apotex derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

43. On information and belief, Apotex markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Apotex Corp., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware. On information and belief, Apotex, through Apotex Corp., is licensed to sell generic pharmaceutical products in the State of Delaware, pursuant to 24 Del. C. § 2540.

44. This Court also has personal jurisdiction because Apotex has filed its ANDAs for VEMLIDY, DESCOVY, and ODEFSEY, seeking approval from the FDA to market and sell

Apotex's VEMLIDY ANDA Product, Apotex's DESCOVY ANDA Product, and Apotex's ODEFSEY ANDA Product (collectively, "Apotex's TAF ANDA Products") throughout the United States, including in Delaware. On information and belief, Apotex intends to commercially manufacture, use, and sell Apotex's TAF ANDA Products upon receiving FDA approval. On information and belief, if and when the FDA approves Apotex's ANDAs, Apotex's TAF ANDA Products would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its ANDAs, Apotex has made clear that it intends to use its distribution channels to direct sales of Apotex's TAF ANDA Products into Delaware.

45. Further, this Court has personal jurisdiction over Apotex because Apotex has previously been sued in this district and has not challenged personal jurisdiction, and Apotex has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Forest Labs. Inc. et al. v. Apotex Corp. et al.*, Civil Action No. 1:14-cv-00200, D.I. 32 (D. Del. May 6, 2014); *Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:07-cv-00779, D.I. 13 (D. Del. Jan. 22, 2008). Upon information and belief, Apotex has also availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g.*, *Apotex, Inc. v. et al. v. Lupin Ltd. et al.*, Civil Action No. 1:15-cv-00357, D.I. 1 (D. Del. May 4, 2015); *Apotex Inc. et al. v. Senju Pharm. Co., Ltd. et al.*, Civil Action No. 1:12-cv-00196, D.I. 1 (D. Del. Feb. 16, 2012).

46. Alternatively, this Court may exercise personal jurisdiction over Apotex pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Apotex is a foreign company not subject to personal jurisdiction in the courts of any state; and

(c) Apotex has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Apotex satisfies due process.

47. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Apotex is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Jurisdiction and Venue for Defendant Lupin

48. This Court has personal jurisdiction over Lupin by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Lupin regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Lupin received more than 75 FDA approvals to market and sell pharmaceutical products throughout the United States, including in Delaware. On information and belief, Lupin derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

49. On information and belief, Lupin markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Lupin Pharmaceuticals, Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware. On information and belief, Lupin, through Lupin Pharmaceuticals, Inc., is licensed to sell generic pharmaceutical products in the State of Delaware, pursuant to 24 Del. C. § 2540.

50. This Court also has personal jurisdiction because Lupin has filed its ANDAs for

VEMLIDY, DESCOVY, and ODEFSEY, seeking approval from the FDA to market and sell Lupin's VEMLIDY ANDA Product, DESCOVY ANDA Product, and ODEFSEY ANDA Product (collectively, "Lupin's TAF ANDA Products") throughout the United States, including in Delaware. On information and belief, Lupin intends to commercially manufacture, use, and sell Lupin's TAF ANDA Products upon receiving FDA approval. On information and belief, if and when the FDA approves Lupin's ANDAs, Lupin's TAF ANDA Products would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its ANDAs, Lupin has made clear that it intends to use its distribution channels to direct sales of Lupin's TAF ANDA Products into Delaware.

51. Further, this Court has personal jurisdiction over Lupin because Lupin has previously been sued in this district and has not challenged personal jurisdiction, and Lupin has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Forest Labs, LLC, et al. v. Lupin Limited, et al.*, Civil Action No. 1:14-cv-01058, D.I. 15 (D. Del. Sept. 8, 2014); *ViiV Healthcare UK Ltd., et al. v. Lupin Ltd, et al.*, Civil Action No. 1:14-cv-00369, D.I. 10 (D. Del. June 12, 2014); *Teijin Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 1:14-cv-00184, D.I. 20 (D. Del. April 1, 2014).

52. Alternatively, this Court may exercise personal jurisdiction over Lupin pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Lupin is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Lupin has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Lupin satisfies due process.

53. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Lupin is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Jurisdiction and Venue for Defendant Laurus Labs

54. This Court has personal jurisdiction over Laurus Labs by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Laurus Labs regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Laurus Labs currently markets and sells at least two pharmaceutical products throughout the United States, including in Delaware. On information and belief, Laurus Labs derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

55. On information and belief, Laurus Labs markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Laurus Generics Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware.

56. This Court also has personal jurisdiction because Laurus Labs has filed its ANDAs for VEMLIDY and DESCOVY, seeking approval from the FDA to market and sell Laurus Labs's VEMLIDY ANDA Product and Laurus Labs's DESCOVY ANDA Product (collectively, "Laurus Labs's TAF ANDA Products") throughout the United States, including in Delaware. On information and belief, Laurus Labs intends to commercially manufacture, use, and sell Laurus

Labs's TAF ANDA Products upon receiving FDA approval. On information and belief, if and when the FDA approves Laurus Labs's ANDAs, Laurus Labs's TAF ANDA Products would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its ANDAs, Laurus Labs has made clear that it intends to use its distribution channels to direct sales of Laurus Labs's TAF ANDA Products into Delaware.

57. Further, this Court has personal jurisdiction over Laurus Labs because Laurus Labs has previously been sued in this district and has not challenged personal jurisdiction, and Laurus Labs has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Genentech, Inc. et al. v. Laurus Labs Ltd. et al.*, Civil Action No. 1:19-cv-00104, D.I. 12 (D. Del. Mar. 7, 2019); *Boehringer Ingelheim Pharma. Inc. et al. v. Laurus Labs Ltd. et al.*, Civil Action No. 1:18-cv-01758, D.I. 13 (D. Del. Jan. 11, 2019).

58. Alternatively, this Court may exercise personal jurisdiction over Laurus Labs pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Laurus Labs is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Laurus Labs has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Laurus Labs satisfies due process.

59. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Laurus Labs is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Jurisdiction and Venue for Defendant Shilpa

60. This Court has personal jurisdiction over Shilpa by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Shilpa regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Shilpa currently markets and sells at least eight pharmaceutical products throughout the United States, including in Delaware. On information and belief, Shilpa derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

61. On information and belief, Shilpa markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Shilpa, Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware.

62. This Court also has personal jurisdiction because Shilpa has filed its ANDA for VEMLIDY, seeking approval from the FDA to market and sell Shilpa's VEMLIDY ANDA Product throughout the United States, including in Delaware. On information and belief, Shilpa intends to commercially manufacture, use, and sell Shilpa's VEMLIDY ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Shilpa's VEMLIDY ANDA, Shilpa's VEMLIDY ANDA Product would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

By filing its VEMLIDY ANDA, Shilpa has made clear that it intends to use its distribution channels to direct sales of Shilpa's VEMLIDY ANDA Product into Delaware.

63. Further, this Court has personal jurisdiction over Shilpa because Shilpa has previously been sued in this district and has not challenged personal jurisdiction, and Shilpa has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Pharmacyclics LLC et al. v. Shilpa Medicare Ltd. et al.*, Civil Action No. 1:18-cv-00237, D.I. 24 (D. Del. May 4, 2018); *Biogen MA Inc. v. Shilpa Medicare Ltd.*, Civil Action No. 1:17-cv-00847, D.I. 8 (D. Del. Oct. 16, 2017).

64. Alternatively, this Court may exercise personal jurisdiction over Shilpa pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Shilpa is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Shilpa has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Shilpa satisfies due process.

65. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Shilpa is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Jurisdiction and Venue for Defendant Sunshine Lake

66. This Court has personal jurisdiction over Sunshine Lake by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Sunshine Lake regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical

products in the United States, including Delaware. On information and belief, Sunshine Lake derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

67. On information and belief, Sunshine Lake markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Sunshine Lake LLC, a Delaware limited liability company that is registered to do business and has appointed an agent to accept service in Delaware.

68. This Court also has personal jurisdiction because Sunshine Lake has filed its ANDAs for VEMLIDY, seeking approval from the FDA to market and sell Sunshine Lake's VEMLIDY ANDA Product throughout the United States, including in Delaware. On information and belief, Sunshine Lake intends to commercially manufacture, use, and sell Sunshine Lake's VEMLIDY ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Sunshine Lake's VEMLIDY ANDA, Sunshine Lake's VEMLIDY ANDA Product would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its VEMLIDY ANDA, Sunshine Lake has made clear that it intends to use its distribution channels to direct sales of Sunshine Lake's VEMLIDY ANDA Product into Delaware.

69. Further, this Court has personal jurisdiction over Sunshine Lake because Sunshine Lake has previously been sued in this district and has not challenged personal jurisdiction, and Sunshine Lake has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Bristol-Myers Squibb Co. et al. v. Sunshine Lake Pharma Co., Ltd., et al.*, Civil Action No. 1:17-cv-00380, D.I. 9 (D. Del. June 26, 2017).

70. Alternatively, this Court may exercise personal jurisdiction over Sunshine Lake pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Sunshine Lake is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Sunshine Lake has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Sunshine Lake satisfies due process.

71. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Sunshine Lake is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Jurisdiction and Venue for Defendant Natco

72. This Court has personal jurisdiction over Natco by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Natco regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Natco currently markets and sells over 20 pharmaceutical products throughout the United States, including in Delaware. On information and belief, Natco derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

73. On information and belief, Natco markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Natco Pharma, Inc., a Delaware

corporation that is registered to do business and has appointed an agent to accept service in Delaware.

74. This Court also has personal jurisdiction because Natco has filed its ANDA for DESCOVY, seeking approval from the FDA to market and sell Natco's DESCOVY ANDA Product throughout the United States, including in Delaware. On information and belief, Natco intends to commercially manufacture, use, and sell Natco's DESCOVY ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Natco's DESCOVY ANDA, Natco's DESCOVY ANDA Product would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its DESCOVY ANDA, Natco has made clear that it intends to use its distribution channels to direct sales of Natco's DESCOVY ANDA Product into Delaware.

75. Further, this Court has personal jurisdiction over Natco because Natco has previously been sued in this district and has not challenged personal jurisdiction, and Natco has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Novartis Pharmaceuticals Corporation et al. v. Natco Pharma Ltd.*, Civil Action No. 1:15-cv-00987, D.I. 12 (D. Del. Jan. 19, 2016); *Shire Canada Inc. et al. v. Natco Pharma Ltd.*, Civil Action No. 1:09-cv-03165, D.I. 36 (D. Del. Jan. 13, 2010).

76. Alternatively, this Court may exercise personal jurisdiction over Natco pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Natco is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Natco has sufficient contacts with the United States as a whole, including but not limited to

marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Natco satisfies due process.

77. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Natco is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Jurisdiction and Venue for Defendant Cipla

78. This Court has personal jurisdiction over Cipla by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Cipla regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Cipla has submitted more than 170 ANDAs to the FDA in order to market and sell pharmaceutical products throughout the United States, including in Delaware. On information and belief, Cipla derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

79. On information and belief, Cipla markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Cipla USA Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware.

80. This Court also has personal jurisdiction because Cipla has filed its ANDAs for DESCOVY, and ODEFSEY, seeking approval from the FDA to market and sell Cipla's

DESCOVY ANDA Product and Cipla's ODEFSEY ANDA Product (collectively, "Cipla's TAF ANDA Products") throughout the United States, including in Delaware. On information and belief, Cipla intends to commercially manufacture, use, and sell Cipla's TAF ANDA Products upon receiving FDA approval. On information and belief, if and when the FDA approves Cipla's ANDAs, Cipla's TAF ANDA Products would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its ANDAs, Cipla has made clear that it intends to use its distribution channels to direct sales of Cipla's TAF ANDA Products into Delaware.

81. Further, this Court has personal jurisdiction over Cipla because Cipla has previously been sued in this district and has not challenged personal jurisdiction, and Cipla has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Biogen Int'l GmbH et al. v. Cipla Ltd. et al.*, Civil Action No. 1:17-cv-00851, D.I. 10 (D. Del. Oct. 16, 2017); *Onyx Therapeutics, Inc. v. Cipla Ltd.*, Civil Action No. 1:16-cv-00988, D.I. 12 (D. Del. Jan. 13, 2017). Upon information and belief, Cipla has also availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g.*, *Cipla Ltd. et al. v. Amgen Inc.*, Civil Action No. 1:19-cv-00044, D.I. 1 (D. Del. Jan. 8, 2019); *Cipla Ltd. v. Sunovion Pharma. Inc.*, Civil Action No. 1:15-cv-00424, D.I. 1 (D. Del. May 26, 2015).

82. Alternatively, this Court may exercise personal jurisdiction over Cipla pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Cipla is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Cipla has sufficient contacts with the United States as a whole, including but not limited to

marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Cipla satisfies due process.

83. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Cipla is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Jurisdiction and Venue for Defendant Macleods

84. This Court has personal jurisdiction over Macleods by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Macleods regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Macleods currently markets and sells over 62 FDA-approved pharmaceutical products throughout the United States, including in Delaware. On information and belief, Macleods derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

85. On information and belief, Macleods markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates including Macleods Pharma USA, Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware.

86. This Court also has personal jurisdiction because Macleods has filed its ANDA for DESCOVY, seeking approval from the FDA to market and sell Macleods's DESCOVY ANDA Product throughout the United States, including in Delaware. On information and belief, Macleods

intends to commercially manufacture, use, and sell Macleods's DESCOVY ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Macleods's DESCOVY ANDA, Macleods's DESCOVY ANDA Product would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its DESCOVY ANDA, Macleods has made clear that it intends to use its distribution channels to direct sales of Macleods's DESCOVY ANDA Product into Delaware.

87. Further, this Court has personal jurisdiction over Macleods because Macleods has previously been sued in this district and has not challenged personal jurisdiction, and Macleods has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Merck Sharp & Dohme Corp. v. Macleods Pharma. Ltd. et al.*, Civil Action No. 1:19-cv-00316, D.I. 11 (D. Del. Apr. 8, 2019); *Biogen Int'l GmbH et al. v. Macleods Pharma., Ltd. et al.*, Civil Action No. 1:17-cv-00857, D.I. 7 (D. Del. July 17, 2017).

88. Alternatively, this Court may exercise personal jurisdiction over Macleods pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Macleods is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Macleods has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Macleods satisfies due process.

89. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Macleods is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

Jurisdiction and Venue for Hetero Defendants

90. This Court has personal jurisdiction over Hetero USA Inc. because, on information and belief, Hetero USA Inc. is incorporated in Delaware.

91. This Court has personal jurisdiction over Hetero Labs Limited and Hetero Labs Limited Unit-V by virtue of, *inter alia*, their systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through their subsidiaries, agents, and/or affiliates, Hetero Labs Limited and Hetero Labs Limited Unit-V regularly and continuously transact business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Hetero Labs Limited and Hetero Labs Limited Unit-V currently markets or sells over 200 pharmaceutical products throughout the United States, including in Delaware. On information and belief, Hetero Labs Limited Unit-V and Hetero Labs Limited derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within Delaware.

92. On information and belief, Hetero Labs Limited and Hetero Labs Limited Unit-V markets and distributes their pharmaceutical products through subsidiaries, agents, and/or affiliates including Hetero USA, Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware. On information and belief, Hetero USA, Inc. is licensed to sell generic pharmaceutical products in the State of Delaware, pursuant to 24 Del. C. § 2540.

93. This Court also has personal jurisdiction over Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V because they, collectively and/or in concert with each

other, filed the Hetero ANDAs for VEMLIDY and DESCOVY, seeking approval from the FDA to market and sell Hetero's VEMLIDY ANDA Product and Hetero's DESCOVY ANDA Product (collectively, "Hetero's TAF ANDA Products") throughout the United States, including in Delaware. On information and belief, Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V, collectively and/or in concert with each other, intend to commercially manufacture, use, and sell Hetero's TAF ANDA Products upon receiving FDA approval. On information and belief, if and when the FDA approves Hetero's ANDAs, Hetero's TAF ANDA Products would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its ANDAs, Hetero USA Inc., Hetero Labs Limited, and Hetero Labs Limited Unit-V have made clear that it intends to use its distribution channels to direct sales of Hetero's TAF ANDA Products into Delaware.

94. Further, this Court has personal jurisdiction over Hetero Labs Limited because it has previously been sued in this district and has not challenged personal jurisdiction, and Hetero Labs Limited has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Biogen Int'l GmbH et al. v. Hetero USA Inc. et al.*, Civil Action No. 1:17-cv-00825, D.I. 13 (D. Del. Oct. 16, 2017); *Bristol-Myers Squibb Co. et al. v. Hetero USA Inc. et al.*, Civil Action No. 1:17-cv-00376, D.I. 9 (D. Del. June 16, 2017).

95. Alternatively, this Court may exercise personal jurisdiction over Hetero Labs Limited and Hetero Labs Limited Unit-V pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Hetero Labs Limited and Hetero Labs Limited Unit-V are a foreign companies not subject to personal jurisdiction in the courts of any state; and (c) Hetero Labs Limited and Hetero Labs Limited Unit-V have sufficient contacts with

the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs Limited and Hetero Labs Limited Unit-V satisfies due process.

96. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) because Hetero Labs Limited and Hetero Labs Limited Unit-V are both foreign corporations and may be sued in any judicial district in the United States in which they are subject to the court's personal jurisdiction, including in this District.

97. Venue is also proper in this District under 28 U.S.C. § 1400(b) because Hetero USA Inc. is a Delaware corporation.

PATENTS-IN-SUIT

98. On June 24, 2008, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 7,390,791 (the "'791 patent"), titled, "Prodrugs of Phosphonate Nucleotide Analogues." A true and correct copy of the '791 patent is attached hereto as Exhibit A. The claims of the '791 patent are valid, enforceable, and not expired. Gilead is the assignee of the '791 patent.

99. On September 28, 2010, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 7,803,788 (the "'788 patent"), titled, "Prodrugs of Phosphonate Nucoleotide [sic] Analogues." A true and correct copy of the '788 patent is attached hereto as Exhibit B. The claims of the '788 patent are valid, enforceable, and not expired. Gilead is the assignee of the '788 patent.

100. On June 17, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,754,065 (the "'065 patent"), titled, "Tenofovir Alafenamide Hemifumarate." A

true and correct copy of the '065 patent is attached hereto as Exhibit C. The claims of the '065 patent are valid, enforceable, and not expired. Gilead is the assignee of the '065 patent.

101. On March 29, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,296,769 (the "'769 patent"), titled, "Tenofovir Alafenamide Hemifumarate." A true and correct copy of the '769 patent is attached hereto as Exhibit D. The claims of the '769 patent are valid, enforceable, and not expired. Gilead is the assignee of the '769 patent.

ACTS GIVING RISE TO THIS ACTION

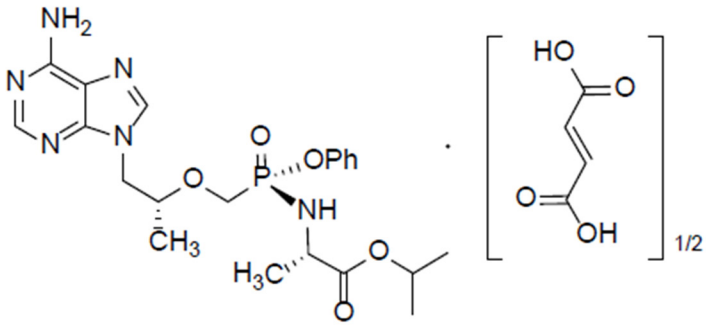
VEMLIDY

102. Gilead holds approved New Drug Application ("NDA") No. 208464 for 25 mg tablets containing tenofovir alafenamide for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease, as further described in the VEMLIDY label.

103. Gilead markets the tablets approved under NDA No. 208464 in the United States under the registered trademark VEMLIDY. FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") identifies the following patents for VEMLIDY: U.S. Patent Nos. 7,390,791; 7,803,788; 8,754,065; and 9,296,769.

104. Gilead describes its VEMLIDY tablets as containing a tenofovir alafenamide fumarate active ingredient with the following empirical and structural formulas:

It has an empirical formula of $C_{21}H_{29}O_5N_6P \cdot ½(C_4H_4O_4)$ and a formula weight of 534.50. It has the following structural formula:



105. Gilead's VEMLIDY tablets contain less than 5% by weight tenofovir alafenamide monofumarate.

106. At least one claim of each of the Patents-In-Suit (all of which are listed in the Orange Book) covers VEMLIDY, or approved methods of using VEMLIDY.

107. Defendants Apotex, Lupin, Laurus Labs, Shilpa, Sunshine Lake, and Hetero filed ANDAs listing VEMLIDY as the reference listed drug ("RLD").

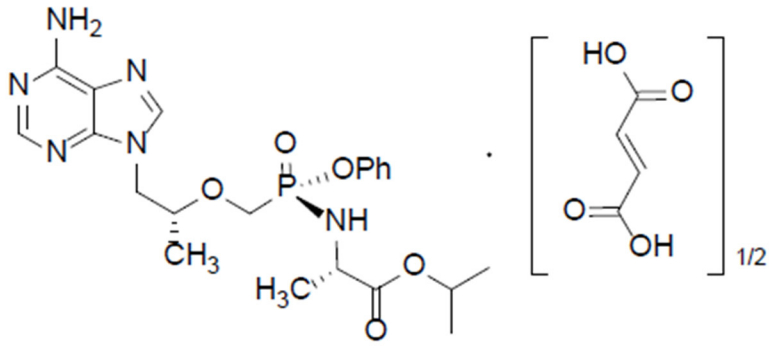
DESCOVY

108. Gilead holds approved NDA No. 208215 for tablets containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide, in combination with other antiretroviral agents, for treatment of HIV-1 infection in adults and pediatric patients, and for at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection, as further described on the DESCOVY label.

109. Gilead markets the tablets approved under NDA No. 208215 in the United States under the registered trademark DESCOVY. The Orange Book identifies the following patents for DESCOVY: U.S. Patent Nos. 6,642,245; 6,703,396; 7,390,791; 7,803,788; 8,754,065; and 9,296,769.

110. Gilead describes its DESCOVY tablets as containing a tenofovir alafenamide fumarate active ingredient, among others, with the following empirical and structural formulas:

Tenofovir alafenamide fumarate has an empirical formula of $C_{21}H_{29}O_5N_6P \cdot \frac{1}{2}(C_4H_4O_4)$ and a formula weight of 534.50 and has the following structural formula:



111. Gilead's DESCOVY tablets contain less than 5% by weight tenofovir alafenamide monofumarate.

112. At least one claim of each of the Patents-In-Suit (all of which are listed in the Orange Book) covers DESCOVY, or approved methods of using DESCOVY.

113. Defendants Apotex, Lupin, Laurus Labs, Natco, Cipla, Macleods, and Hetero filed ANDAs listing DESCOVY as the RLD.

ODEFSEY

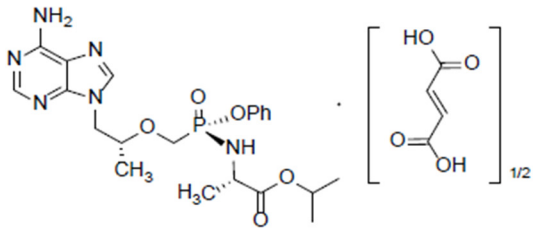
114. Gilead holds approved NDA No. 208351 for tablets containing 200 mg emtricitabine, 25 mg of rilpivirine, and 25 mg of tenofovir alafenamide for the treatment of HIV-1 infection in adults and pediatric patients either as an initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL or to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) for at least 6 months with no history of treatment failure and no known substitutions

associated with resistance to the individual components of the tablets, as further described on the ODEFSEY label.

115. Gilead markets the tablets approved under NDA No. 208351 in the United States under the registered trademark ODEFSEY. The Orange Book identifies the following patents for ODEFSEY: U.S. Patent Nos. 6,642,245; 6,703,396; 6,838,464; 7,125,879; 7,390,791; 7,803,788; 8,080,551; 8,101,629; 8,754,065; and 9,296,769.

116. Gilead describes its ODEFSEY tablets as containing a tenofovir alafenamide fumarate active ingredient, among others, with the following empirical and structural formulas:

Tenofovir alafenamide fumarate has an empirical formula of $C_{21}H_{29}O_5N_6P \cdot ½(C_4H_4O_4)$ and a formula weight of 534.50 and has the following structural formula:



117. Gilead's ODEFSEY tablets contain less than 5% by weight tenofovir alafenamide monofumarate.

118. At least one claim of each of the Patents-In-Suit (all of which are listed in the Orange Book) covers ODEFSEY, or approved methods of using ODEFSEY.

119. Defendants Apotex, Lupin, and Cipla filed ANDAs listing ODEFSEY as the RLD.

Apotex's Acts Regarding VEMLIDY

120. On information and belief, Apotex submitted to the FDA its VEMLIDY ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (the "FFDCA"), seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Apotex's VEMLIDY ANDA Product before the

expiration of the '065 and '769 patents. On information and belief, the FDA assigned Apotex the ANDA number 213867.

121. On information and belief, Apotex sent a letter dated December 30, 2019 to Gilead ("Apotex's VEMLIDY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Apotex's VEMLIDY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

122. Gilead received Apotex's VEMLIDY Notice Letter on or about December 31, 2019.

123. This action is being commenced before the expiration of 45 days from the date Gilead received Apotex's VEMLIDY Notice Letter, which triggers a stay of FDA approval of Apotex's VEMLIDY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

124. By filing its VEMLIDY ANDA, Apotex has necessarily represented to FDA that its VEMLIDY ANDA Product has the same active ingredient as VEMLIDY; has the same dosage form and strength as VEMLIDY; and is bioequivalent to VEMLIDY.

125. On information and belief, Apotex is seeking approval to market its VEMLIDY ANDA Product for the same approved indication as VEMLIDY.

126. On information and belief, Apotex's proposed label for its VEMLIDY ANDA Product ("Apotex's Proposed VEMLIDY Label") will refer to the product as, *inter alia*, a hepatitis B virus nucleoside analog reverse transcriptase inhibitor for the treatment of chronic hepatitis B infection in adults with compensated liver disease, and will describe the tablet strength of Apotex's VEMLIDY ANDA Product as 25 mg.

127. On information and belief, Apotex's Proposed VEMLIDY Label will instruct physicians and healthcare providers to administer Apotex's VEMLIDY ANDA Product for, *inter*

alia, the treatment of chronic hepatitis B infection in adults with compensated liver disease.

128. On information and belief, Apotex's Proposed VEMLIDY Label will contain data relating to the treatment of patients with hepatitis B infection, obtained from clinical studies involving, *inter alia*, VEMLIDY.

Apotex's Acts Regarding DESCOVY

129. On information and belief, Apotex submitted to the FDA its DESCOVY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Apotex's DESCOVY ANDA Product before the expiration of the '065 and '769 patents. On information and belief, the FDA assigned Apotex the ANDA number 214053.

130. On information and belief, Apotex sent a letter dated December 30, 2019 to Gilead ("Apotex's DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Apotex's DESCOVY Notice Letter includes certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

131. Gilead received Apotex's DESCOVY Notice Letter on or about December 31, 2019.

132. This action is being commenced before the expiration of 45 days from the date Gilead received Apotex's DESCOVY Notice Letter, which triggers a stay of FDA approval of Apotex's DESCOVY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

133. By filing its DESCOVY ANDA, Apotex has necessarily represented to FDA that its DESCOVY ANDA product has the same active ingredients as DESCOVY; has the same dosage forms and strengths as DESCOVY; and is bioequivalent to DESCOVY.

134. On information and belief, Apotex is seeking approval to market its DESCOVY ANDA Product for the same approved indications as DESCOVY.

135. On information and belief, Apotex's proposed label for its DESCOVY ANDA Product ("Apotex's Proposed DESCOVY Label") will refer to the product as, *inter alia*, a two-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and for at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide.

136. On information and belief, Apotex's Proposed DESCOVY Label will instruct physicians and healthcare providers to administer Apotex's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in adults and pediatric patients, and at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

137. On information and belief, Apotex's Proposed DESCOVY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, DESCOVY.

Apotex's Acts Regarding ODEFSEY

138. On information and belief, Apotex submitted to the FDA its ODEFSEY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Apotex's ODEFSEY ANDA Product before the expiration of the '065 and '769 patents. On information and belief, the FDA assigned Apotex the ANDA number 214095.

139. On information and belief, Apotex sent a letter dated December 30, 2019 to Gilead ("Apotex's ODEFSEY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Apotex's ODEFSEY Notice Letter includes certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

140. Gilead received the Apotex ODEFSEY Notice Letter on or about December 31, 2019.

141. This action is being commenced before the expiration of 45 days from the date Gilead received Apotex's ODEFSEY Notice Letter, which triggers a stay of FDA approval of Apotex's ODEFSEY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

142. By filing its ODEFSEY ANDA, Apotex has necessarily represented to FDA that its ODEFSEY ANDA Product has the same active ingredients as ODEFSEY; has the same dosage forms and strengths as ODEFSEY; and is bioequivalent to ODEFSEY.

143. On information and belief, Apotex is seeking approval to market its ODEFSEY ANDA Product for the same approved indication as ODEFSEY.

144. On information and belief, Apotex's proposed label for its ODEFSEY ANDA Product ("Apotex's Proposed ODEFSEY Label") will refer to the product as, *inter alia*, a three-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, and rilpivirine, a non-nucleoside reverse transcriptase inhibitor, as a complete regimen for the treatment of HIV-1 infection in patients, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine, 25 mg of rilpivirine, and 25 mg of tenofovir alafenamide.

145. On information and belief, Apotex's Proposed ODEFSEY Label will instruct physicians and healthcare providers to administer Apotex's ODEFSEY ANDA Product for, *inter*

alia, the treatment of HIV-1 infection in patients.

146. On information and belief, Apotex's Proposed ODEFSEY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, ODEFSEY.

Lupin's Acts Regarding VEMLIDY

147. On information and belief, Lupin submitted to the FDA its VEMLIDY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Lupin's VEMLIDY ANDA Product before the expiration of all four Patents-In-Suit. On information and belief, the FDA assigned Lupin the ANDA number 214226.

148. On information and belief, Lupin sent a letter dated January 2, 2020 to Gilead ("Lupin's VEMLIDY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Lupin's VEMLIDY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to all four Patents-In-Suit.

149. Gilead received Lupin's VEMLIDY Notice Letter on or about January 3, 2020.

150. This action is being commenced before the expiration of 45 days from the date Gilead received VEMLIDY Notice Letter, which triggers a stay of FDA approval of Lupin's VEMLIDY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

151. By filing its VEMLIDY ANDA, Lupin has necessarily represented to FDA that its VEMLIDY ANDA product has the same active ingredient as VEMLIDY; has the same dosage form and strength as VEMLIDY; and is bioequivalent to VEMLIDY.

152. On information and belief, Lupin is seeking approval to market its VEMLIDY ANDA Product for the same approved indication as VEMLIDY.

153. On information and belief, Lupin's proposed label for its VEMLIDY ANDA Product ("Lupin's Proposed VEMLIDY Label") will refer to the product as, *inter alia*, a hepatitis B virus nucleoside analog reverse transcriptase inhibitor for the treatment of chronic hepatitis B infection in adults with compensated liver disease, and will describe the tablet strength of Lupin's VEMLIDY ANDA Product as 25 mg.

154. On information and belief, Lupin's Proposed VEMLIDY Label will instruct physicians and healthcare providers to administer Lupin's VEMLIDY ANDA Product for, *inter alia*, the treatment of chronic hepatitis B infection in adults with compensated liver disease.

155. On information and belief, Lupin's Proposed VEMLIDY Label will contain data relating to the treatment of patients with hepatitis B infection, obtained from clinical studies involving, *inter alia*, VEMLIDY.

Lupin's Acts Regarding DESCOVY

156. On information and belief, Lupin submitted to the FDA its DESCOVY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Lupin's DESCOVY ANDA Product before the expiration of all four Patents-In-Suit. On information and belief, the FDA assigned Lupin ANDA number 213926.

157. On information and belief, Lupin sent a letter dated January 2, 2020 to Gilead ("Lupin's DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Lupin's DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to all four Patents-In-Suit.

158. Gilead received Lupin's DESCOVY Notice Letter on or about January 3, 2020.

159. This action is being commenced before the expiration of 45 days from the date

Gilead received Lupin's DESCOVY Notice Letter, which triggers a stay of FDA approval of Lupin's DESCOVY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

160. By filing its DESCOVY ANDA, Lupin has necessarily represented to FDA that its DESCOVY ANDA product has the same active ingredients as DESCOVY; has the same dosage forms and strengths as DESCOVY; and is bioequivalent to DESCOVY.

161. On information and belief, Lupin is seeking approval to market its DESCOVY ANDA Product for the same approved indications as DESCOVY.

162. On information and belief, Lupin's proposed label for its DESCOVY ANDA Product ("Lupin's Proposed DESCOVY Label") will refer to the product as, *inter alia*, a two-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and for at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide.

163. On information and belief, Lupin's Proposed DESCOVY Label will instruct physicians and healthcare providers to administer Lupin's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in adults and pediatric patients, and at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

164. On information and belief, Lupin's Proposed DESCOVY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, DESCOVY.

Lupin's Acts Regarding ODEFSEY

165. On information and belief, Lupin submitted to the FDA its ODEFSEY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Lupin's ODEFSEY ANDA Product before the expiration of all four Patents-In-Suit. On information and belief, the FDA assigned Lupin ANDA number 214227.

166. On information and belief, Lupin sent a letter dated January 2, 2020 to Gilead ("Lupin's ODEFSEY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Lupin's ODEFSEY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to all four Patents-In-Suit.

167. Gilead received the Lupin ODEFSEY Notice Letter on or about January 3, 2020.

168. This action is being commenced before the expiration of 45 days from the date Gilead received Lupin's ODEFSEY Notice Letter, which triggers a stay of FDA approval of Lupin's ODEFSEY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

169. By filing its ODEFSEY ANDA, Lupin has necessarily represented to FDA that its ODEFSEY ANDA Product has the same active ingredients as ODEFSEY; has the same dosage forms and strengths as ODEFSEY; and is bioequivalent to ODEFSEY.

170. On information and belief, Lupin is seeking approval to market its ODEFSEY ANDA Product for the same approved indication as ODEFSEY.

171. On information and belief, Lupin's proposed label for its ODEFSEY ANDA Product ("Lupin's Proposed ODEFSEY Label") will refer to the product as, *inter alia*, a three-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, and rilpivirine, a non-nucleoside reverse transcriptase inhibitor, as a

complete regimen for the treatment of HIV-1 infection in patients, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine, 25 mg of rilpivirine, and 25 mg of tenofovir alafenamide.

172. On information and belief, Lupin's Proposed ODEFSEY Label will instruct physicians and healthcare providers to administer Lupin's ODEFSEY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in patients.

173. On information and belief, Lupin's Proposed ODEFSEY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, ODEFSEY.

Laurus Labs's Acts Regarding VEMLIDY

174. On information and belief, Laurus Labs submitted to the FDA its VEMLIDY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Laurus Labs's VEMLIDY ANDA Product before the expiration of the '791, '065, and '769 patents. On information and belief, the FDA assigned Laurus Labs ANDA number 214030.

175. On information and belief, Laurus Labs sent a letter dated January 6, 2020 to Gilead ("Laurus Labs's First VEMLIDY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Laurus Labs's First VEMLIDY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

176. On information and belief, Laurus Labs sent a second letter dated October 7, 2020 to Gilead ("Laurus Labs's Second VEMLIDY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Laurus Labs's Second VEMLIDY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '791 patent.

177. Gilead received Laurus Labs's First VEMLIDY Notice Letter on or about January 7, 2020, and Laurus Labs's Second VEMLIDY Notice Letter on or about October 8, 2020.

178. Gilead filed its initial complaint in this matter before the expiration of 45 days from the date Gilead received Laurus Labs's First VEMLIDY Notice Letter, which triggered a stay of FDA approval of Laurus Labs's VEMLIDY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

179. Gilead filed its first amended complaint before the expiration of 45 days from the date Gilead received Laurus Labs's Second VEMLIDY Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii).

180. By filing its VEMLIDY ANDA, Laurus Labs has necessarily represented to FDA that its VEMLIDY ANDA product has the same active ingredient as VEMLIDY; has the same dosage form and strength as VEMLIDY; and is bioequivalent to VEMLIDY.

181. On information and belief, Laurus Labs is seeking approval to market its VEMLIDY ANDA Product for the same approved indication as VEMLIDY.

182. On information and belief, Laurus Labs's proposed label for its VEMLIDY ANDA Product ("Laurus Labs's Proposed VEMLIDY Label") will refer to the product as, *inter alia*, a hepatitis B virus nucleoside analog reverse transcriptase inhibitor for the treatment of chronic hepatitis B infection in adults with compensated liver disease, and will describe the tablet strength of Laurus Labs's VEMLIDY ANDA Product as 25 mg.

183. On information and belief, Laurus Labs's Proposed VEMLIDY Label will instruct physicians and healthcare providers to administer Laurus Labs's VEMLIDY ANDA Product for, *inter alia*, the treatment of chronic hepatitis B infection in adults with compensated liver disease.

184. On information and belief, Laurus Labs's Proposed VEMLIDY Label will contain data relating to the treatment of patients with hepatitis B infection, obtained from clinical studies involving, *inter alia*, VEMLIDY.

Laurus Labs's Acts Regarding DESCOVY

185. On information and belief, Laurus Labs has submitted to the FDA its DESCOVY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Laurus Labs's DESCOVY ANDA Product before the expiration of the '791, '065, and '769 patents. On information and belief, the FDA assigned Laurus Labs the ANDA number 213989.

186. On information and belief, Laurus Labs sent a letter dated January 7, 2020 to Gilead ("Laurus Labs's First DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Laurus Labs's DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769.

187. On information and belief, Laurus Labs sent a second letter dated October 7, 2020 to Gilead ("Laurus Labs's Second DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Laurus Labs's Second DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '791 patent.

188. Gilead received Laurus Labs's First DESCOVY Notice Letter on or about January 8, 2020, and Laurus Labs's Second DESCOVY Notice Letter on or about October 8, 2020.

189. Gilead filed its initial complain in this matter before the expiration of 45 days from the date Gilead received Laurus Labs's First DESCOVY Notice Letter, which triggered a stay of FDA approval of Laurus Labs's DESCOVY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

190. Gilead filed its first amended complaint before the expiration of 45 days from the

date Gilead received Laurus Labs's Second DESCOVY Notice Letter in accordance with 21 U.S.C. § 355(j)(5)(B)(iii).

191. By filing its DESCOVY ANDA, Laurus Labs has necessarily represented to FDA that its DESCOVY ANDA product has the same active ingredients as DESCOVY; has the same dosage forms and strengths as DESCOVY; and is bioequivalent to DESCOVY.

192. On information and belief, Laurus Labs is seeking approval to market its DESCOVY ANDA Product for the same approved indications as DESCOVY.

193. On information and belief, Laurus Labs's proposed label for its DESCOVY ANDA Product (Laurus Labs's "Proposed DESCOVY Label") will refer to the product as, *inter alia*, a two-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and for at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide.

194. On information and belief, Laurus Labs's Proposed DESCOVY Label will instruct physicians and healthcare providers to administer Laurus Labs's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in adults and pediatric patients, and at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

195. On information and belief, Laurus Labs's Proposed DESCOVY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, DESCOVY.

Shilpa's Acts Regarding VEMLIDY

196. On information and belief, Shilpa submitted to the FDA its VEMLIDY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Shilpa's VEMLIDY ANDA Product before the expiration of the '065 and '769 patents. On information and belief, the FDA assigned Shilpa ANDA number 214072.

197. On information and belief, Shilpa sent a letter dated January 2, 2020 to Gilead ("Shilpa's VEMLIDY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Shilpa's VEMLIDY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

198. Gilead received Shilpa's VEMLIDY Notice Letter on or about January 3, 2020.

199. This action is being commenced before the expiration of 45 days from the date Gilead received Shilpa's VEMLIDY Notice Letter, which triggers a stay of FDA approval of Shilpa's VEMLIDY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

200. By filing its VEMLIDY ANDA, Shilpa has necessarily represented to FDA that its VEMLIDY ANDA product has the same active ingredient as VEMLIDY; has the same dosage form and strength as VEMLIDY; and is bioequivalent to VEMLIDY.

201. On information and belief, Shilpa is seeking approval to market its VEMLIDY ANDA Product for the same approved indication as VEMLIDY.

202. On information and belief, Shilpa's proposed label for its VEMLIDY ANDA Product ("Shilpa's Proposed VEMLIDY Label") will refer to the product as, *inter alia*, a hepatitis B virus nucleoside analog reverse transcriptase inhibitor for the treatment of chronic hepatitis B infection in adults with compensated liver disease, and will describe the tablet strength of Shilpa's

VEMLIDY ANDA Product as 25 mg.

203. On information and belief, Shilpa's Proposed VEMLIDY Label will instruct physicians and healthcare providers to administer Shilpa's VEMLIDY ANDA Product for, *inter alia*, the treatment of chronic hepatitis B infection in adults with compensated liver disease.

204. On information and belief, Shilpa's Proposed VEMLIDY Label will contain data relating to the treatment of patients with hepatitis B infection, obtained from clinical studies involving, *inter alia*, VEMLIDY.

Sunshine Lake's Acts Regarding VEMLIDY

205. On information and belief, Sunshine Lake submitted to the FDA its VEMLIDY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Sunshine Lake's VEMLIDY ANDA Product before the expiration of the '065 and '769 patents. On information and belief, the FDA assigned Sunshine Lake ANDA number 213845.

206. On information and belief, Sunshine Lake sent a letter dated January 2, 2020 to Gilead ("Sunshine Lake's VEMLIDY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Sunshine Lake's VEMLIDY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

207. Gilead received Sunshine Lake's VEMLIDY Notice Letter on or about January 3, 2020.

208. This action is being commenced before the expiration of 45 days from the date Gilead received Sunshine Lake's VEMLIDY Notice Letter, which triggers a stay of FDA approval of Sunshine Lake's VEMLIDY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

209. By filing its VEMLIDY ANDA, Sunshine Lake has necessarily represented to FDA that its VEMLIDY ANDA product has the same active ingredient as VEMLIDY; has the same dosage form and strength as VEMLIDY; and is bioequivalent to VEMLIDY.

210. On information and belief, Sunshine Lake is seeking approval to market its VEMLIDY ANDA Product for the same approved indication as VEMLIDY.

211. On information and belief, Sunshine Lake's proposed label for its VEMLIDY ANDA Product ("Sunshine Lake's Proposed VEMLIDY Label") will refer to the product as, *inter alia*, a hepatitis B virus nucleoside analog reverse transcriptase inhibitor for the treatment of chronic hepatitis B infection in adults with compensated liver disease, and will describe the tablet strength of Sunshine Lake's VEMLIDY ANDA Product as 25 mg.

212. On information and belief, Sunshine Lake's Proposed VEMLIDY Label will instruct physicians and healthcare providers to administer Sunshine Lake's VEMLIDY ANDA Product for, *inter alia*, the treatment of chronic hepatitis B infection in adults with compensated liver disease.

213. On information and belief, Sunshine Lake's Proposed VEMLIDY Label will contain data relating to the treatment of patients with hepatitis B infection, obtained from clinical studies involving, *inter alia*, VEMLIDY.

Natco's Acts Regarding DESCOVY

214. On information and belief, Natco has submitted to the FDA its DESCOVY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Natco's DESCOVY ANDA Product before the expiration of the '791, '065, and '769 patents. On information and belief, the FDA assigned Natco ANDA number 214173.

215. On information and belief, Natco sent a letter dated January 7, 2020 to Gilead ("Natco's First DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Natco's First DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

216. On information and belief, Natco sent a second letter dated January 21, 2020 to Gilead ("Natco's Second DESCOVY Notice Letter"), purporting to be a notice of recertification pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.96(d)(1)(i). Natco's Recertification DESCOVY Notice Letter purports to incorporate Natco's First DESCOVY Notice Letter. Natco's Recertification DESCOVY Notice Letter also purports to have been made with regard to certain use codes associated with the '065 and '769 patents.

217. On information and belief, Natco sent a third letter dated October 15, 2020 to Gilead ("Natco's Third DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Natco's Third DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '791 patent.

218. Gilead received Natco's First DESCOVY Notice Letter on or about January 8, 2020, Natco's Second DESCOVY Notice Letter on or about January 22, 2020, and Natco's Third DESCOVY Notice Letter on or about October 16, 2020..

219. Gilead filed its initial complaint in this matter before the expiration of 45 days from the date Gilead received Natco's First DESCOVY Notice Letter, which triggered a stay of FDA approval of Natco's DESCOVY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

220. Gilead filed its first amended complaint before the expiration of 45 days from the date Gilead received Natco's Third DESCOVY Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii).

221. By filing its DESCOVY ANDA, Natco has necessarily represented to FDA that its DESCOVY ANDA product has the same active ingredient as DESCOVY; has the same dosage forms and strengths as DESCOVY; and is bioequivalent to DESCOVY.

222. On information and belief, Natco is seeking approval to market its DESCOVY ANDA Product for the same approved indications as DESCOVY.

223. On information and belief, Natco's proposed label for its DESCOVY ANDA Product ("Natco's Proposed DESCOVY Label") will refer to the product as, *inter alia*, a two-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and for at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide.

224. On information and belief, Natco's Proposed DESCOVY Label will instruct physicians and healthcare providers to administer Natco's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in adults and pediatric patients, and at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

225. On information and belief, Natco's Proposed DESCOVY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, DESCOVY.

Cipla's Acts Regarding DESCOVY

226. On information and belief, Cipla submitted to the FDA its DESCOVY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial

manufacture, use, importation, offer for sale, and/or sale of Cipla's DESCOVY ANDA Product before the expiration of all four Patents-In-Suit. On information and belief, the FDA assigned Cipla ANDA number 214059.

227. On information and belief, Cipla sent a letter dated January 10, 2020 to Gilead ("Cipla's First DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Cipla's First DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '064 and '769 patents.

228. On information and belief, Cipla sent a second letter dated January 10, 2020 to Gilead ("Cipla's Second DESCOVY Notice Letter"), also purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Cipla's Second DESCOVY Notice Letter purports to incorporate Cipla's First DESCOVY Notice Letter. Cipla's Second DESCOVY Notice Letter also includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '791 and '788 patents.

229. Gilead received Cipla's First DESCOVY Notice Letter on or about January 13, 2020, and Cipla's Second DESCOVY Notice Letter on or about January 13, 2020.

230. This action is being commenced before the expiration of 45 days from the date Gilead received Cipla's DESCOVY Notice Letter, which triggers a stay of FDA approval of Cipla's DESCOVY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

231. By filing its DESCOVY ANDA, Cipla has necessarily represented to FDA that its DESCOVY ANDA product has the same active ingredients as DESCOVY; has the same dosage forms and strengths as DESCOVY; and is bioequivalent to DESCOVY.

232. On information and belief, Cipla is seeking approval to market its DESCOVY ANDA Product for the same approved indications as DESCOVY.

233. On information and belief, Cipla's proposed label for its DESCOVY ANDA Product ("Cipla's Proposed DESCOVY Label") will refer to the product as, *inter alia*, a two-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and for at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide.

234. On information and belief, Cipla's Proposed DESCOVY Label will instruct physicians and healthcare providers to administer Cipla's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in adults and pediatric patients, and at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

235. On information and belief, Cipla's Proposed DESCOVY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, DESCOVY.

Cipla's Acts Regarding ODEFSEY

236. On information and belief, Cipla submitted to the FDA its ODEFSEY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Cipla's ODEFSEY ANDA Product before the expiration of all four Patents-In-Suit. On information and belief, the FDA assigned Cipla ANDA number 214058.

237. On information and belief, Cipla sent a letter dated January 9, 2020 to Gilead ("Cipla's First ODEFSEY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C.

§ 355(j)(2)(B). Cipla's First ODEFSEY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '064 and '769 patents.

238. On information and belief, Cipla sent a second letter dated January 10, 2020 to Gilead ("Cipla's Second ODEFSEY Notice Letter"), also purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Cipla's Second ODEFSEY Notice Letter purports to incorporate Cipla's First ODEFSEY Notice Letter. Cipla's Second ODEFSEY Notice Letter also includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '791 and '788 patents

239. Gilead received Cipla's First ODEFSEY Notice Letter on or about January 10, 2020, and Cipla's Second ODEFSEY Notice Letter on or about January 13, 2020.

240. This action is being commenced before the expiration of 45 days from the date Gilead received either of Cipla's ODEFSEY Notice Letters, which triggers a stay of FDA approval of Cipla's ODEFSEY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

241. By filing its ODEFSEY ANDA, Cipla has necessarily represented to FDA that its ODEFSEY ANDA Product has the same active ingredients as ODEFSEY; has the same dosage forms and strengths as ODEFSEY; and is bioequivalent to ODEFSEY.

242. On information and belief, Cipla is seeking approval to market its ODEFSEY ANDA Product for the same approved indications as ODEFSEY.

243. On information and belief, Cipla's proposed label for its ODEFSEY ANDA Product ("Cipla's Proposed ODEFSEY Label") will refer to the product as, *inter alia*, a three-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, and rilpivirine, a non-nucleoside reverse transcriptase inhibitor, as a complete regimen for the treatment of HIV-1 infection in patients, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine, 25 mg of rilpivirine, and 25 mg of

tenofovir alafenamide.

244. On information and belief, Cipla's Proposed ODEFSEY Label will instruct physicians and healthcare providers to administer Cipla's ODEFSEY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in patients.

245. On information and belief, Cipla's Proposed ODEFSEY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, ODEFSEY.

Macleods's Acts Regarding DESCOVY

246. On information and belief, Macleods submitted to the FDA its DESCOVY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Macleods's DESCOVY ANDA Product before the expiration of the '065 and '769 patents. On information and belief, the FDA assigned Macleods ANDA number 214216.

247. On information and belief, Macleods sent a letter dated January 14, 2020 to Gilead ("Macleods's DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Macleods's DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

248. Gilead received Macleods's DESCOVY Notice Letter on or about January 16, 2020.

249. This action is being commenced before the expiration of 45 days from the date Gilead received Macleods's DESCOVY Notice Letter, which triggers a stay of FDA approval of Macleods's DESCOVY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

250. By filing its DESCOVY ANDA, Macleods has necessarily represented to FDA that its DESCOVY ANDA product has the same active ingredients as DESCOVY; has the same dosage forms and strengths as DESCOVY; and is bioequivalent to DESCOVY.

251. On information and belief, Macleods is seeking approval to market its DESCOVY ANDA Product for the same approved indications as DESCOVY.

252. On information and belief, Macleods's proposed label for its DESCOVY ANDA Product ("Macleods's Proposed DESCOVY Label") will refer to the product as, *inter alia*, a two-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and for at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection, and will describe the fixed-dose combination tablets as containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide.

253. On information and belief, Macleods's Proposed DESCOVY Label will instruct physicians and healthcare providers to administer Macleods's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in adults and pediatric patients, and at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

254. On information and belief, Macleods's Proposed DESCOVY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, DESCOVY.

Hetero's Acts Regarding VEMLIDY

255. On information and belief, Hetero has submitted to the FDA its VEMLIDY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial

manufacture, use, importation, offer for sale, and/or sale of Hetero's VEMLIDY ANDA Product before the expiration of the '791, '065 and '769 patents. On information and belief, the FDA assigned Hetero ANDA number 214179.

256. On information and belief, Hetero sent a letter dated January 15, 2020 to Gilead ("Hetero's First VEMLIDY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's First VEMLIDY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

257. On information and belief, Hetero sent a second letter dated September 29, 2021 to Gilead ("Hetero's Second VEMLIDY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's Second VEMLIDY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '791 patent

258. Gilead received Hetero's First VEMLIDY Notice Letter on or about January 16, 2020 and Hetero's Second VEMLIDY Notice Letter on or about September 30, 2021.

259. Gilead filed its initial complaint in this matter before the expiration of 45 days from the date Gilead received Hetero's First VEMLIDY Notice Letter, which triggered a stay of FDA approval of Hetero's VEMLIDY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

260. Gilead is filing this second amended complaint before the expiration of 45 days from the date Gilead received Hetero's Second VEMLIDY Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii).

261. By filing its VEMLIDY ANDA, Hetero has necessarily represented to FDA that its VEMLIDY ANDA product has the same active ingredient as VEMLIDY; has the same dosage form and strength as VEMLIDY; and is bioequivalent to VEMLIDY.

262. On information and belief, Hetero is seeking approval to market its VEMLIDY ANDA Product for the same approved indication as VEMLIDY.

263. On information and belief, Hetero's proposed label for its VEMLIDY ANDA Product ("Hetero's Proposed VEMLIDY Label") will refer to the product as, *inter alia*, a hepatitis B virus nucleoside analog reverse transcriptase inhibitor for the treatment of chronic hepatitis B infection in adults with compensated liver disease, and will describe the tablet strength of Hetero's VEMLIDY ANDA Product as 25 mg.

264. On information and belief, Hetero's Proposed VEMLIDY Label will instruct physicians and healthcare providers to administer Hetero's VEMLIDY ANDA Product for, *inter alia*, the treatment of chronic hepatitis B infection in adults with compensated liver disease.

265. On information and belief, Hetero's Proposed VEMLIDY Label will contain data relating to the treatment of patients with hepatitis B infection, obtained from clinical studies involving, *inter alia*, VEMLIDY.

Hetero's Acts Regarding DESCOVY

266. On information and belief, Hetero has submitted to the FDA its DESCOVY ANDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Hetero's DESCOVY ANDA Product before the expiration of the '791, '065 and '769 patents. On information and belief, the FDA assigned Hetero ANDA number 211850.

267. On information and belief, Hetero sent a letter dated January 15, 2020 to Gilead (Hetero's First "DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's First DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '065 and '769 patents.

268. On information and belief, Hetero sent a letter dated September 23, 2021 to Gilead (Hetero's Second "DESCOVY Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's Second DESCOVY Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '791 patent.

269. Gilead received Hetero's First DESCOVY Notice Letter on or about January 16, 2020 and Hetero's Second DESCOVY Notice Letter on or about September 24, 2021.

270. Gilead filed its initial complaint in this matter before the expiration of 45 days from the date Gilead received Hetero's First DESCOVY Notice Letter, which triggered a stay of FDA approval of Hetero's DESCOVY ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

271. Gilead is filing this second amended complaint before the expiration of 45 days from the date Gilead received Hetero's Second DESCOVY Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii).

272. By filing its DESCOVY ANDA, Hetero has necessarily represented to FDA that its DESCOVY ANDA product has the same active ingredients as DESCOVY; has the same dosage forms and strengths as DESCOVY; and is bioequivalent to DESCOVY.

273. On information and belief, Hetero is seeking approval to market its DESCOVY ANDA Product for the same approved indications as DESCOVY.

274. On information and belief, Hetero's proposed label for its DESCOVY ANDA Product ("Hetero's Proposed DESCOVY Label") will refer to the product as, *inter alia*, a two-drug combination of emtricitabine and tenofovir alafenamide, both HIV nucleoside analog reverse transcriptase inhibitors, used in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients, and for at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection, and will describe the fixed-

dose combination tablets as containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide.

275. On information and belief, Hetero's Proposed DESCOVY Label will instruct physicians and healthcare providers to administer Hetero's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in adults and pediatric patients, and at-risk adults and adolescents for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

276. On information and belief, Hetero's Proposed DESCOVY Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving, *inter alia*, DESCOVY.

Gilead's Attempts to Gain Access to Defendants' ANDAs

277. Defendants' Notice Letters each included an Offer for Confidential Access ("OCA") to their respective ANDAs on terms and conditions set forth in each Notice Letter. The OCAs requested that Gilead accept the terms of each OCA before receiving access to that Defendants' ANDAs. Under 35 U.S.C. 355(j)(5)(C)(i)(III), an OCA "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." Defendants' OCAs each contained unreasonable restrictions, above and beyond those that would apply under a protective order.

278. Since receiving Defendants' Notice Letters, Gilead and each of the Defendants have been negotiating in good faith to reach a mutually-acceptable agreement under which Defendants would provide their ANDAs to Gilead. To date, each Defendant has refused to offer Gilead access to its ANDA under terms consistent with a protective order entered for the purpose

of protecting trade secrets and other confidential business information. As a result, Gilead has been unable to access Defendants' ANDAs.

279. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate, pursuant to 21 U.S.C. § 355(c)(3)(C).

280. Gilead is not aware of any other means of obtaining information regarding Defendants' TAF ANDA Products within the 45-day statutory period. In the absence of such information, Gilead resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief, and to present to the Court evidence, that Defendants have and will infringe certain claims of the Patents-In-Suit.

COUNTS I-XII AGAINST APOTEX

VEMLIDY Counts

Count I: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Apotex's VEMLIDY ANDA Product

281. Gilead realleges the foregoing paragraphs as if fully set forth herein.

282. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the '065 patent by submitting Apotex's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's VEMLIDY ANDA Product in the United States prior to the expiration of the '065 patent.

283. Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's VEMLIDY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one

of the claims of the '065 patent, including but not limited to claim 1.[1]

284. On information and belief, for example, Apotex's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

285. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

286. Unless and until Apotex is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count II: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Apotex's VEMLIDY ANDA Product

287. Gilead realleges the foregoing paragraphs as if fully set forth herein.

288. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

289. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

290. Apotex has submitted an ANDA for a generic version of Gilead's VEMLIDY product. According to Apotex's VEMLIDY Notice Letter, Apotex intends to manufacture, use, offer for sale, sell, and/or import Apotex's VEMLIDY ANDA Product in the United States.

291. While the FDA has not yet approved Apotex's VEMLIDY ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's VEMLIDY ANDA Product.

[1] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

292. Apotex's actions indicate that it does not intend to change its course of conduct.

293. On information and belief, upon FDA approval of Apotex's VEMLIDY ANDA, Apotex will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[2] by making, using, offering to sell, and/or selling Apotex's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

294. On information and belief, for example, Apotex's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

295. Apotex has actual knowledge of the '065 patent.

296. On information and belief, Apotex became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

297. On information and belief, Apotex's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent.

298. On information and belief, Apotex's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Apotex in the United States by it or on its behalf.

[2] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

299. On information and belief, Apotex's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Apotex's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent.

300. On information and belief, physicians and healthcare providers will administer Apotex's VEMLIDY ANDA Product in the United States according to the directions and instructions in the Apotex's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

301. On information and belief, at least through its Proposed VEMLIDY Label, Apotex will encourage physicians and healthcare providers to administer Apotex's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent, and Apotex will know or should know that such conduct will occur.

302. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

303. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '065 patent.

304. On information and belief, Apotex knows or should know that Apotex's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the '065 patent and that Apotex's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

305. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's VEMLIDY ANDA Product will contribute to the actual infringement of the '065 patent.

306. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '065 patent.

307. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '065 patent.

308. On information and belief, if Apotex's VEMLIDY ANDA is approved by the FDA, Apotex will make its VEMLIDY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

309. On information and belief, Apotex's VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Apotex's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

310. Through at least the foregoing actions, Apotex will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

311. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's VEMLIDY ANDA Product by Apotex prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

312. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

313. Unless and until Apotex is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count III: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Apotex's VEMLIDY ANDA Product

314. Gilead realleges the foregoing paragraphs as if fully set forth herein.

315. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the'769 patent by submitting Apotex's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's VEMLIDY ANDA Product in the United States prior to the expiration of the '769 patent.

316. Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's VEMLIDY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[3]

317. On information and belief, for example, Apotex's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

318. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

319. Unless and until Apotex is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count IV: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Apotex's VEMLIDY ANDA Product

[3] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

320. Gilead realleges the foregoing paragraphs as if fully set forth herein.

321. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

322. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

323. Apotex has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Apotex's VEMLIDY Notice Letter, Apotex intends to manufacture, use, offer for sale, sell, and/or import Apotex's VEMLIDY ANDA Product within the United States.

324. While the FDA has not yet approved Apotex's VEMLIDY ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's VEMLIDY ANDA Product.

325. Apotex's actions indicate that it does not intend to change its course of conduct.

326. On information and belief, upon FDA approval of Apotex's VEMLIDY ANDA, Apotex will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[4] by making, using, offering to sell, and/or selling Apotex's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

327. On information and belief, for example, Apotex's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition

[4] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

328. Apotex has actual knowledge of the '769 patent.

329. On information and belief, Apotex became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

330. On information and belief, Apotex's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent.

331. On information and belief, Apotex's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Apotex in the United States by it or on its behalf.

332. On information and belief, Apotex's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Apotex's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent.

333. On information and belief, physicians and healthcare providers will administer Apotex's VEMLIDY ANDA Product in the United States according to the directions and instructions in Apotex's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

334. On information and belief, at least through its Proposed VEMLIDY Label, Apotex

will encourage physicians and healthcare providers to administer Apotex's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent, and Apotex will know or should know that such conduct will occur.

335. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

336. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '769 patent.

337. On information and belief, Apotex knows or should know that Apotex's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Apotex's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

338. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

339. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

340. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '769 patent.

341. On information and belief, if Apotex's VEMLIDY ANDA is approved by the FDA, Apotex will make its VEMLIDY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

342. On information and belief, Apotex's VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Apotex's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

343. Through at least the foregoing actions, Apotex will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

344. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's VEMLIDY ANDA Product by Apotex prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

345. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

346. Unless and until Apotex is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

DESCOVY Counts

Count V: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Apotex's DESCOVY ANDA Product

347. Gilead realleges the foregoing paragraphs as if fully set forth herein.

348. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the '065 patent by submitting Apotex's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's DESCOVY ANDA Product in the United States prior to the expiration of the '065 patent.

349. Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's DESCOVY ANDA Product prior to the expiration of the '065 patent, and its

inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[5]

350. On information and belief, for example, Apotex's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

351. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

352. Unless and until Apotex is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count VI: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Apotex's DESCOVY ANDA Product

353. Gilead realleges the foregoing paragraphs as if fully set forth herein.

354. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

355. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

356. Apotex has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Apotex's DESCOVY Notice Letter, Apotex intends to manufacture, use, offer for sale, sell, and/or import Apotex's DESCOVY ANDA Product within the United States.

[5] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

357. While the FDA has not yet approved Apotex's DESCOVY ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's DESCOVY ANDA Product.

358. Apotex's actions indicate that it does not intend to change its course of conduct.

359. On information and belief, upon FDA approval of Apotex's DESCOVY ANDA, Apotex will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[6] by making, using, offering to sell, and/or selling Apotex's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

360. On information and belief, for example, Apotex's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

361. Apotex has actual knowledge of the '065 patent.

362. On information and belief, Apotex became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book as covering DESCOVY.

363. On information and belief, Apotex's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent.

[6] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

364. On information and belief, Apotex's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Apotex in the United States by it or on its behalf.

365. On information and belief, Apotex's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Apotex's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent.

366. On information and belief, physicians and healthcare providers will administer Apotex's DESCOVY ANDA Product in the United States according to the directions and instructions in Apotex's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

367. On information and belief, at least through its Proposed DESCOVY Label, Apotex will encourage physicians and healthcare providers to administer Apotex's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent, and Apotex will know or should know that such conduct will occur.

368. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

369. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '065 patent.

370. On information and belief, Apotex knows or should know that Apotex's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '065 patent and that Apotex's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

371. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's DESCOVY ANDA Product will contribute to the actual infringement of the '065 patent.

372. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '065 patent.

373. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '065 patent.

374. On information and belief, if Apotex's DESCOVY ANDA is approved by the FDA, Apotex will make its DESCOVY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

375. On information and belief, Apotex's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Apotex's DESCOVY ANDA Product become a trivial and nonessential component of another product.

376. Through at least the foregoing actions, Apotex will infringe of at least one claim of the '065 patent under 35 U.S.C. § 271(g).

377. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's DESCOVY ANDA Product by Apotex prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

378. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

379. Unless and until Apotex is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count VII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Apotex's DESCOVY ANDA Product

380. Gilead realleges the foregoing paragraphs as if fully set forth herein.

381. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the '769 patent by submitting Apotex's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's DESCOVY ANDA Product in the United States prior to the expiration of the '769 patent.

382. Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's DESCOVY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[7]

383. On information and belief, for example, Apotex's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

384. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's

[7] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

385. Unless and until Apotex is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count VIII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Apotex's DESCOVY ANDA Product

386. Gilead realleges the foregoing paragraphs as if fully set forth herein.

387. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

388. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

389. Apotex has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Apotex's DESCOVY Notice Letter, Apotex intends to manufacture, use, offer for sale, sell, and/or import Apotex's DESCOVY ANDA Product within the United States.

390. While the FDA has not yet approved Apotex's DESCOVY ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's DESCOVY ANDA Product.

391. Apotex's actions indicate that it does not intend to change its course of conduct.

392. On information and belief, upon FDA approval of Apotex's DESCOVY ANDA, Apotex will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[8] by making, using, offering to sell, and/or selling

[8] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

Apotex's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

393. On information and belief, for example, Apotex's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

394. Apotex has actual knowledge of the '769 patent.

395. On information and belief, Apotex became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

396. On information and belief, Apotex's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent.

397. On information and belief, Apotex's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Apotex in the United States by it or on its behalf.

398. On information and belief, Apotex's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Apotex's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

399. On information and belief, physicians and healthcare providers will administer Apotex's DESCOVY ANDA Product in the United States according to the directions and instructions in Apotex's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

400. On information and belief, at least through its Proposed DESCOVY Label, Apotex will encourage physicians and healthcare providers to administer Apotex's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Apotex will know or should know that such conduct will occur.

401. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

402. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claims of the '769 patent.

403. On information and belief, Apotex knows or should know that Apotex's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Apotex's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

404. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

405. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

406. Through at least the foregoing actions, Apotex will contribute to the infringement

of at least one claim of the '769 patent.

407. On information and belief, if Apotex's DESCOVY ANDA is approved by the FDA, Apotex will make its DESCOVY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

408. On information and belief, Apotex's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Apotex's DESCOVY ANDA Product become a trivial and nonessential component of another product.

409. Through at least the foregoing actions, Apotex will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

410. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's DESCOVY ANDA Product by Apotex prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

411. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

412. Unless and until Apotex is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

ODEFSEY Counts

Count IX: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Apotex's ODEFSEY ANDA Product

413. Gilead realleges the foregoing paragraphs as if fully set forth herein.

414. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the '065 patent by submitting Apotex's ODEFSEY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ODEFSEY ANDA Product in the United States prior to the expiration of the '065 patent.

415. Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ODEFSEY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[9]

416. On information and belief, for example, Apotex's ODEFSEY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

417. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

418. Unless and until Apotex is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count X: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Apotex's ODEFSEY ANDA Product

419. Gilead realleges the foregoing paragraphs as if fully set forth herein.

420. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[9] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

421. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

422. Apotex has submitted an ANDA for a generic version of Gilead's ODEFSEY pharmaceutical product. According to Apotex's ODEFSEY Notice Letter, Apotex intends to manufacture, use, offer for sale, sell, and/or import Apotex's ODEFSEY ANDA Product within the United States.

423. While the FDA has not yet approved Apotex's ODEFSEY ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's ODEFSEY ANDA Product.

424. Apotex's actions indicate that it does not intend to change its course of conduct.

425. On information and belief, upon FDA approval of Apotex's ODEFSEY ANDA, Apotex will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[10] by making, using, offering to sell, and/or selling Apotex's ODEFSEY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

426. On information and belief, for example, Apotex's ODEFSEY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

427. Apotex has actual knowledge of the '065 patent.

[10] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

428. On information and belief, Apotex became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book as covering ODEFSEY.

429. On information and belief, Apotex's efforts to make, use, sell, offer for sell, and/or import its ODEFSEY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent.

430. On information and belief, Apotex's ODEFSEY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Apotex in the United States by it or on its behalf.

431. On information and belief, Apotex's Proposed ODEFSEY Label will include directions and instructions that instruct physicians and healthcare providers to administer Apotex's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '065 patent.

432. On information and belief, physicians and healthcare providers will administer Apotex's ODEFSEY ANDA Product in the United States according to the directions and instructions in Apotex's Proposed ODEFSEY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

433. On information and belief, at least through its Proposed ODEFSEY Label, Apotex will encourage physicians and healthcare providers to administer Apotex's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '065 patent, and Apotex will know or should know that such conduct will occur.

434. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the ’065 patent.

435. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the ’065 patent.

436. On information and belief, Apotex knows or should know that Apotex’s ODEFSEY ANDA Product will be especially made or adapted for use in infringing the ’065 patent and that Apotex’s ODEFSEY ANDA Product is not suitable for substantial non-infringing use.

437. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex’s ODEFSEY ANDA Product will contribute to the actual infringement of the ’065 patent.

438. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of its ODEFSEY ANDA Product will contribute to the actual infringement of the ’065 patent.

439. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the ’065 patent.

440. On information and belief, if Apotex’s ODEFSEY ANDA is approved by the FDA, Apotex will make its ODEFSEY ANDA Product using a process covered by one or more claims of the ’065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

441. On information and belief, Apotex’s ODEFSEY ANDA Product will not be materially changed by a subsequent process nor will Apotex’s ODEFSEY ANDA Product become a trivial and nonessential component of another product.

442. Through at least the foregoing actions, Apotex will infringe at least one claim of

the ’065 patent under 35 U.S.C. § 271(g).

443. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex’s ODEFSEY ANDA Product by Apotex prior to the expiration of the ’065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’065 patent.

444. The commercial manufacture, importation, use, sale, or offer for sale of Apotex’s ODEFSEY ANDA Product in violation of Gilead’s patent rights will cause harm to Gilead for which damages are inadequate.

445. Unless and until Apotex is enjoined from infringing the ’065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XI: Infringement of the ’769 Patent under 35 U.S.C. § 271(e)(2) by Apotex’s ODEFSEY ANDA Product

446. Gilead realleges the foregoing paragraphs as if fully set forth herein.

447. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the ’769 patent by submitting Apotex’s ODEFSEY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’s ODEFSEY ANDA Product in the United States prior to the expiration of the ’769 patent.

448. Apotex’s commercial manufacture, use, offer for sale, sale, and/or importation of Apotex’s ODEFSEY ANDA Product prior to the expiration of the ’769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the ’769 patent, including but not limited to claim 1.[11]

[11] Gilead will identify all asserted claims of the ’769 patent in accordance with this Court’s Local Rules and/or scheduling order.

449. On information and belief, for example, Apotex's ODEFSEY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

450. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

451. Unless and until Apotex is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Apotex's ODEFSEY ANDA Product

452. Gilead realleges the foregoing paragraphs as if fully set forth herein.

453. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

454. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

455. Apotex has submitted an ANDA for a generic version of Gilead's ODEFSEY pharmaceutical product. According to Apotex's ODEFSEY Notice Letter, Apotex intends to manufacture, use, offer for sale, sell, and/or import Apotex's ODEFSEY ANDA Product within the United States.

456. While the FDA has not yet approved Apotex's ODEFSEY ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Apotex's ODEFSEY ANDA Product.

457. Apotex's actions indicate that it does not intend to change its course of conduct.

458. On information and belief, upon FDA approval of Apotex's ODEFSEY ANDA, Apotex will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[12] by making, using, offering to sell, and/or selling Apotex's ODEFSEY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

459. On information and belief, for example, Apotex's ODEFSEY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

460. Apotex has actual knowledge of the '769 patent.

461. On information and belief, Apotex became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's ODEFSEY product.

462. On information and belief, Apotex's efforts to make, use, sell, offer for sell, and/or import its ODEFSEY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent.

[12] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

463. On information and belief, Apotex's ODEFSEY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Apotex in the United States by it or on its behalf.

464. On information and belief, Apotex's Proposed ODEFSEY Label will include directions and instructions that instruct physicians and healthcare providers to administer Apotex's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

465. On information and belief, physicians and healthcare providers will administer Apotex's ODEFSEY ANDA Product in the United States according to the directions and instructions in Apotex's Proposed ODEFSEY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

466. On information and belief, at least through its Proposed ODEFSEY Label, Apotex will encourage physicians and healthcare providers to administer Apotex's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Apotex will know or should know that such conduct will occur.

467. On information and belief, Apotex will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

468. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '769 patent.

469. On information and belief, Apotex knows or should know that Apotex's ODEFSEY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that

Apotex's ODEFSEY ANDA Product is not suitable for substantial non-infringing use.

470. The commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ODEFSEY ANDA Product will contribute to the actual infringement of the '769 patent.

471. On information and belief, Apotex knows or should know that its offer for sale, sale and/or importation of its ODEFSEY ANDA Product will contribute to the actual infringement of the '769 patent.

472. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '769 patent.

473. On information and belief, if Apotex's ODEFSEY ANDA is approved by the FDA, Apotex will make its ODEFSEY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

474. On information and belief, Apotex's ODEFSEY ANDA Product will not be materially changed by a subsequent process nor will Apotex's ODEFSEY ANDA Product become a trivial and nonessential component of another product.

475. Through at least the foregoing actions, Apotex will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

476. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Apotex's ODEFSEY ANDA Product by Apotex prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

477. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for

which damages are inadequate.

478. Unless and until Apotex is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNTS XIII-XXVIII AGAINST LUPIN

VEMLIDY Counts

Count XIII: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Lupin's VEMLIDY ANDA Product

479. Gilead realleges the foregoing paragraphs as if fully set forth herein.

480. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of the '065 patent by submitting Lupin's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's VEMLIDY ANDA Product in the United States prior to the expiration of the '065 patent.

481. Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's VEMLIDY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[13]

482. On information and belief, for example, Lupin's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

483. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

[13] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

484. Unless and until Lupin is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XIV: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Lupin's VEMLIDY ANDA Product

485. Gilead realleges the foregoing paragraphs as if fully set forth herein.

486. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

487. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

488. Lupin has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Lupin's VEMLIDY Notice Letter, Lupin intends to manufacture, use, offer for sale, sell, and/or import Lupin's VEMLIDY ANDA Product within the United States.

489. While the FDA has not yet approved Lupin's VEMLIDY ANDA, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Lupin's VEMLIDY ANDA Product.

490. Lupin's actions indicate that it does not intend to change its course of conduct.

491. On information and belief, upon FDA approval of Lupin's VEMLIDY ANDA, Lupin will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[14] by making, using, offering to sell, and/or selling Lupin's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by

[14] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

492. On information and belief, for example, Lupin's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

493. Lupin has actual knowledge of the '065 patent.

494. On information and belief, Lupin became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

495. On information and belief, Lupin's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Lupin's VEMLIDY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

496. On information and belief, Lupin's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Lupin in the United States by it or on its behalf.

497. On information and belief, Lupin's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Lupin's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent.

498. On information and belief, physicians and healthcare providers will administer Lupin's VEMLIDY ANDA Product in the United States according to the directions and instructions in Lupin's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

499. On information and belief, at least through its Proposed VEMLIDY Label, Lupin will encourage physicians and healthcare providers to administer Lupin's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent, and Lupin will know or should know that such conduct will occur.

500. On information and belief, Lupin will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

501. Through at least the foregoing actions, Lupin will actively induce the infringement of at least one claims of the '065 patent.

502. On information and belief, Lupin knows or should know that Lupin's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the '065 patent and that Lupin's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

503. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's VEMLIDY ANDA Product will contribute to the actual infringement of the '065 patent.

504. On information and belief, Lupin knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '065 patent.

505. Through at least the foregoing actions, Lupin will contribute to the infringement of at least one claim of the '065 patent.

506. On information and belief, if Lupin's VEMLIDY ANDA is approved by the FDA, Lupin will make its VEMLIDY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

507. On information and belief, Lupin's VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Lupin's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

508. Through at least the foregoing actions, Lupin will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

509. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Lupin's VEMLIDY ANDA Product by Lupin prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

510. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

511. Unless and until Lupin is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XV: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Lupin's VEMLIDY ANDA Product

512. Gilead realleges the foregoing paragraphs as if fully set forth herein.

513. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of the '769 patent by submitting Lupin's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's VEMLIDY ANDA Product in the United States prior to the expiration of the '769 patent.

514. Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's VEMLIDY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[15]

515. On information and belief, for example, Lupin's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

516. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

517. Unless and until Lupin is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XVI: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Lupin's VEMLIDY ANDA Product

518. Gilead realleges the foregoing paragraphs as if fully set forth herein.

519. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[15] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

520. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

521. Lupin has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Lupin's VEMLIDY Notice Letter, Lupin intends to manufacture, use, offer for sale, sell, and/or import Lupin's VEMLIDY ANDA Product within the United States.

522. While the FDA has not yet approved Lupin's VEMLIDY ANDA, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Lupin's VEMLIDY ANDA Product.

523. Lupin's actions indicate that it does not intend to change its course of conduct.

524. On information and belief, upon FDA approval of Lupin's VEMLIDY ANDA, Lupin will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[16] by making, using, offering to sell, and/or selling Lupin's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

525. On information and belief, for example, Lupin's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls

[16] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

526. Lupin has actual knowledge of the '769 patent.

527. On information and belief, Lupin became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

528. On information and belief, Lupin's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Lupin's VEMLIDY Notice Letter, which does not contest infringement of at least claim 1 of the '769 patent, except on the basis that the claim is allegedly invalid.

529. On information and belief, Lupin's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Lupin in the United States by it or on its behalf.

530. On information and belief, Lupin's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Lupin's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent.

531. On information and belief, physicians and healthcare providers will administer Lupin's VEMLIDY ANDA Product in the United States according to the directions and instructions in Lupin's Proposed VEMLIDY Label, and such administration will constitute direct

infringement of at least one claim of the '769 patent.

532. On information and belief, at least through its Proposed VEMLIDY Label, Lupin will encourage physicians and healthcare providers to administer Lupin's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent, and Lupin will know or should know that such conduct will occur.

533. On information and belief, Lupin will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

534. Through at least the foregoing actions, Lupin will actively induce the infringement of at least one claim of the '769 patent.

535. On information and belief, Lupin knows or should know that Lupin's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Lupin's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

536. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

537. On information and belief, Lupin knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

538. Through at least the foregoing actions, Lupin will contribute to the infringement of at least one claim of the '769 patent.

539. On information and belief, if Lupin's VEMLIDY ANDA is approved by the FDA, Lupin will make its VEMLIDY ANDA Product using a process covered by one or more claims of

the ’769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

540. On information and belief, Lupin’s VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Lupin’s VEMLIDY ANDA Product become a trivial and nonessential component of another product.

541. Through at least the foregoing actions, Lupin will infringe at least one claim of the ’769 patent under 35 U.S.C. § 271(g).

542. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Lupin’s VEMLIDY ANDA Product by Lupin prior to the expiration of the ’769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’769 patent.

543. The commercial manufacture, importation, use, sale, or offer for sale of Lupin’s VEMLIDY ANDA Product in violation of Gilead’s patent rights will cause harm to Gilead for which damages are inadequate.

544. Unless and until Lupin is enjoined from infringing the ’769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

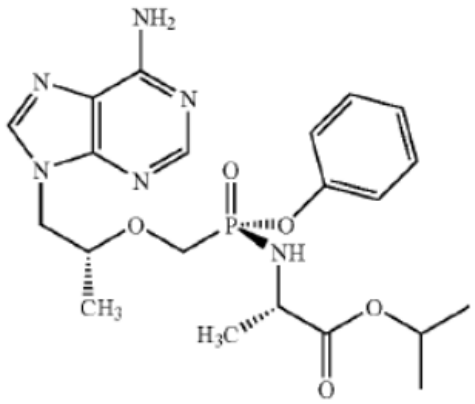
Count XVII: Infringement of the ’791 Patent under 35 U.S.C. § 271(e)(2) by Lupin’s VEMLIDY ANDA Product

545. Gilead realleges the foregoing paragraphs as if fully set forth herein.

546. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of the ’791 patent by submitting Lupin’s VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin’s VEMLIDY ANDA Product in the United States prior to the expiration of the ’791 patent.

547. Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of the VEMLIDY ANDA Product prior to the expiration of the '791 patent would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[17]

548. On information and belief, for example, Lupin's VEMLIDY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

549. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

550. Unless and until Lupin is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XVIII: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Lupin's VEMLIDY ANDA Product

551. Gilead realleges the foregoing paragraphs as if fully set forth herein.

[17] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

552. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

553. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

554. Lupin has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Lupin's VEMLIDY Notice Letter, Lupin intends to manufacture, use, offer for sale, sell, and/or import its VEMLIDY ANDA Product within the United States.

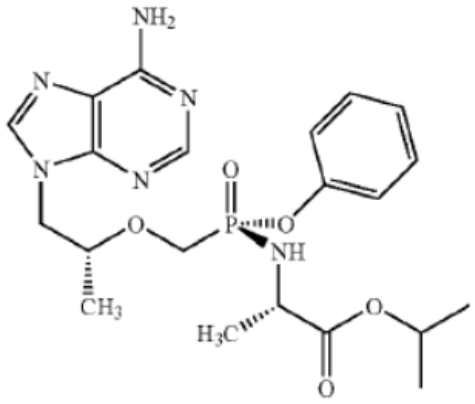
555. While the FDA has not yet approved Lupin's VEMLIDY ANDA, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its VEMLIDY ANDA Product.

556. Lupin's actions indicate that it does not intend to change its course of conduct.

557. On information and belief, upon FDA approval of Lupin's VEMLIDY ANDA, Lupin will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[18] by making, using, offering to sell, and/or selling Lupin's VEMLIDY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

558. On information and belief, for example, Lupin's VEMLIDY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:

[18] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

559. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Lupin's VEMLIDY ANDA Product by Lupin prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

560. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

561. Unless and until Lupin is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

DESCOVY Counts

Count XIX: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Lupin's DESCOVY ANDA Product

562. Gilead realleges the foregoing paragraphs as if fully set forth herein.

563. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of the '065 patent by submitting Lupin's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's DESCOVY ANDA Product in the United States prior to the expiration of the '065 patent.

564. Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's DESCOVY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[19]

565. On information and belief, for example, Lupin's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

566. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

567. Unless and until Lupin is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XX: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Lupin's DESCOVY ANDA Product

568. Gilead realleges the foregoing paragraphs as if fully set forth herein.

569. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

570. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

571. Lupin has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Lupin's DESCOVY Notice Letter, Lupin intends to

[19] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

manufacture, use, offer for sale, sell, and/or import Lupin's DESCOVY ANDA Product within the United States.

572. While the FDA has not yet approved Lupin's DESCOVY ANDA, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Lupin's DESCOVY ANDA Product.

573. Lupin's actions indicate that it does not intend to change its course of conduct.

574. On information and belief, upon FDA approval of Lupin's DESCOVY ANDA, Lupin will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[20] by making, using, offering to sell, and/or selling Lupin's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

575. On information and belief, for example, Lupin's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

576. Lupin has actual knowledge of the '065 patent.

577. On information and belief, Lupin became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

578. On information and belief, Lupin's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of

[20] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

the ’065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’065 patent. On information and belief, this knowledge is reflected through, among other things, Lupin’s DESCOVY Notice Letter, which does not contest infringement of at least claim 1 of the ’065 patent, except on the basis that the claim is allegedly invalid.

579. On information and belief, Lupin’s DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Lupin in the United States by it or on its behalf.

580. On information and belief, Lupin’s Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Lupin’s DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the ’065 patent.

581. On information and belief, physicians and healthcare providers will administer Lupin’s DESCOVY ANDA Product in the United States according to the directions and instructions in Lupin’s Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the ’065 patent.

582. On information and belief, at least through its Proposed DESCOVY Label, Lupin will encourage physicians and healthcare providers to administer Lupin’s DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the ’065 patent, and Lupin will know or should know that such conduct will occur.

583. On information and belief, Lupin will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the ’065 patent.

584. Through at least the foregoing actions, Lupin will actively induce the infringement of at least one claim of the ’065 patent.

585. On information and belief, Lupin knows or should know that Lupin’s DESCOVY ANDA Product will be especially made or adapted for use in infringing the ’065 patent and that Lupin’s DESCOVY ANDA Product is not suitable for substantial non-infringing use.

586. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin’s DESCOVY ANDA Product will contribute to the actual infringement of the ’065 patent.

587. On information and belief, Lupin knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the ’065 patent.

588. Through at least the foregoing actions, Lupin will contribute to the infringement of at least one claim of the ’065 patent.

589. On information and belief, if Lupin’s DESCOVY ANDA is approved by the FDA, Lupin will make its DESCOVY ANDA Product using a process covered by one or more claims of the ’065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

590. On information and belief, Lupin’s DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Lupin’s DESCOVY ANDA Product become a trivial and nonessential component of another product.

591. Through at least the foregoing actions, Lupin will infringe at least one claim of

the ’065 patent under 35 U.S.C. § 271(g).

592. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Lupin’s DESCOVY ANDA Product by Lupin prior to the expiration of the ’065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’065 patent.

593. The commercial manufacture, importation, use, sale, or offer for sale of Lupin’s DESCOVY ANDA Product in violation of Gilead’s patent rights will cause harm to Gilead for which damages are inadequate.

594. Unless and until Lupin is enjoined from infringing the ’065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXI: Infringement of the ’769 Patent under 35 U.S.C. § 271(e)(2) by Lupin’s DESCOVY ANDA Product

595. Gilead realleges the foregoing paragraphs as if fully set forth herein.

596. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of the ’769 patent by submitting Lupin’s DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin’s DESCOVY ANDA Product in the United States prior to the expiration of the ’769 patent.

597. Lupin’s commercial manufacture, use, offer for sale, sale, and/or importation of Lupin’s DESCOVY ANDA Product prior to the expiration of the ’769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the ’769 patent, including but not limited to claim 1.[21]

[21] Gilead will identify all asserted claims of the ’769 patent in accordance with this Court’s Local Rules and/or scheduling order.

598. On information and belief, for example, Lupin's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

599. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

600. Unless and until Lupin is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Lupin's DESCOVY ANDA Product

601. Gilead realleges the foregoing paragraphs as if fully set forth herein.

602. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

603. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

604. Lupin has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Lupin's DESCOVY Notice Letter, Lupin intends to manufacture, use, offer for sale, sell, and/or import Lupin's DESCOVY ANDA Product within the United States.

605. While the FDA has not yet approved Lupin's DESCOVY ANDA, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Lupin's DESCOVY ANDA Product.

606. Lupin's actions indicate that it does not intend to change its course of conduct.

607. On information and belief, upon FDA approval of Lupin's DESCOVY ANDA, Lupin will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[22] by making, using, offering to sell, and/or selling Lupin's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

608. On information and belief, for example, Lupin's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

609. Lupin has actual knowledge of the '769 patent.

610. On information and belief, Lupin became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

611. On information and belief, Lupin's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Lupin's DESCOVY Notice Letter, which

[22] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

does not contest infringement of at least claim 1 of the '769 patent, except on the basis that the claim is allegedly invalid.

612. On information and belief, Lupin's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Lupin in the United States by it or on its behalf.

613. On information and belief, Lupin's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Lupin's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

614. On information and belief, physicians and healthcare providers will administer Lupin's DESCOVY ANDA Product in the United States according to the directions and instructions in Lupin's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

615. On information and belief, at least through its Proposed DESCOVY Label, Lupin will encourage physicians and healthcare providers to administer Lupin's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Lupin will know or should know that such conduct will occur.

616. On information and belief, Lupin will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

617. Through at least the foregoing actions, Lupin will actively induce the infringement of at least one claim of the '769 patent.

618. On information and belief, Lupin knows or should know that Lupin's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Lupin's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

619. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

620. On information and belief, Lupin knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

621. Through the foregoing actions, Lupin will contribute to the infringement of at least one claim of the '769 patent.

622. On information and belief, if Lupin's DESCOVY ANDA is approved by the FDA, Lupin will make its DESCOVY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

623. On information and belief, Lupin's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Lupin's DESCOVY ANDA Product become a trivial and nonessential component of another product.

624. Through at least the foregoing actions, Lupin will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

625. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Lupin's DESCOVY ANDA Product by Lupin prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

626. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

627. Unless and until Lupin is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXIII: Infringement of the '791 Patent under 35 U.S.C. § 271(e)(2) by Lupin's DESCOVY ANDA Product

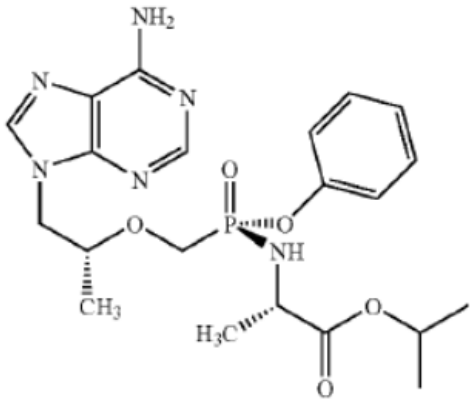
628. Gilead realleges the foregoing paragraphs as if fully set forth herein.

629. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of the '791 patent by submitting Lupin's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's DESCOVY ANDA Product in the United States prior to the expiration of the '791 patent.

630. Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of the DESCOVY ANDA Product prior to the expiration of the '791 patent would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[23]

631. On information and belief, for example, Lupin's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:

[23] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

632. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

633. Unless and until Lupin is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXIV: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Lupin's DESCOVY ANDA Product

634. Gilead realleges the foregoing paragraphs as if fully set forth herein.

635. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

636. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

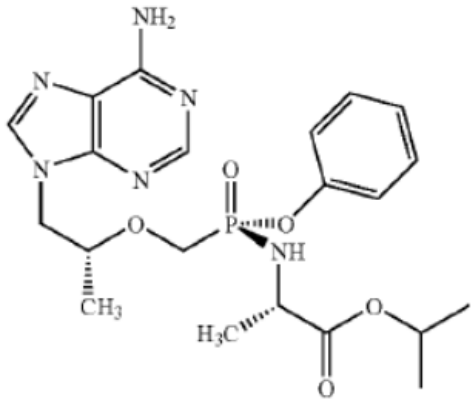
637. Lupin has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Lupin's DESCOVY Notice Letter, Lupin intends to manufacture, use, offer for sale, sell, and/or import its DESCOVY ANDA Product within the United States.

638. While the FDA has not yet approved Lupin's DESCOVY ANDA, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its DESCOVY ANDA Product.

639. Lupin's actions indicate that it does not intend to change its course of conduct.

640. On information and belief, upon FDA approval of Lupin's DESCOVY ANDA, Lupin will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[24] by making, using, offering to sell, and/or selling Lupin's DESCOVY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

641. On information and belief, for example, Lupin's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

642. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for

[24] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

sale, sale, and/or importation of Lupin's DESCOVY ANDA Product by Lupin prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

643. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

644. Unless and until Lupin is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

ODEFSEY Counts

Count XXV: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Lupin's ODEFSEY ANDA Product

645. Gilead realleges the foregoing paragraphs as if fully set forth herein.

646. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of the '065 patent by submitting Lupin's ODEFSEY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ODEFSEY ANDA Product in the United States prior to the expiration of the '065 patent.

647. Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ODEFSEY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[25]

648. On information and belief, for example, Lupin's ODEFSEY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

[25] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

649. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

650. Unless and until Lupin is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXVI: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Lupin's ODEFSEY ANDA Product

651. Gilead realleges the foregoing paragraphs as if fully set forth herein.

652. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

653. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

654. Lupin has submitted an ANDA for a generic version of Gilead's ODEFSEY pharmaceutical product. According to Lupin's ODEFSEY Notice Letter, Lupin intends to manufacture, use, offer for sale, sell, and/or import Lupin's ODEFSEY ANDA Product within the United States.

655. While the FDA has not yet approved Lupin's ODEFSEY ANDA, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Lupin's ODEFSEY ANDA Product.

656. Lupin's actions indicate that it does not intend to change its course of conduct.

657. On information and belief, upon FDA approval of Lupin's ODEFSEY ANDA, Lupin will infringe one or more claims of the '065 patent, either literally or under the doctrine of

equivalents, including but not limited to claim 1,[26] by making, using, offering to sell, and/or selling Lupin's ODEFSEY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

658. On information and belief, for example, Lupin's ODEFSEY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

659. Lupin has actual knowledge of the '065 patent.

660. On information and belief, Lupin became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's ODEFSEY product.

661. On information and belief, Lupin's efforts to make, use, sell, offer for sell, and/or import its ODEFSEY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Lupin's ODEFSEY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

662. On information and belief, Lupin's ODEFSEY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Lupin in the United States by it or on its behalf.

[26] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

663. On information and belief, Lupin's Proposed ODEFSEY Label will include directions and instructions that instruct physicians and healthcare providers to administer Lupin's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '065 patent.

664. On information and belief, physicians and healthcare providers will administer Lupin's ODEFSEY ANDA Product in the United States according to the directions and instructions in Lupin's Proposed ODEFSEY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

665. On information and belief, at least through its Proposed ODEFSEY Label, Lupin will encourage physicians and healthcare providers to administer Lupin's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '065 patent, and Lupin will know or should know that such conduct will occur.

666. On information and belief, Lupin will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

667. Through at least the foregoing actions, Lupin will actively induce the infringement of at least one claim of the '065 patent.

668. On information and belief, Lupin knows or should know that Lupin's ODEFSEY ANDA Product will be especially made or adapted for use in infringing the '065 patent and that Lupin's ODEFSEY ANDA Product is not suitable for substantial non-infringing use.

669. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's ODEFSEY ANDA Product will contribute to the actual infringement of the '065 patent.

670. On information and belief, Lupin knows or should know that its offer for sale, sale and/or importation of its ODEFSEY ANDA Product will contribute to the actual infringement of the '065 patent.

671. Through at least the foregoing actions, Lupin will contribute to the infringement of at least one claim of the '065 patent.

672. On information and belief, if Lupin's ODEFSEY ANDA is approved by the FDA, Lupin will make its ODEFSEY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

673. On information and belief, Lupin's ODEFSEY ANDA Product will not be materially changed by a subsequent process nor will Lupin's ODEFSEY ANDA Product become a trivial and nonessential component of another product.

674. Through at least the foregoing actions, Lupin will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

675. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Lupin's ODEFSEY ANDA Product by Lupin prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

676. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

677. Unless and until Lupin is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXVII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Lupin's ODEFSEY ANDA Product

678. Gilead realleges the foregoing paragraphs as if fully set forth herein.

679. Pursuant to 35 U.S.C. § 271(e)(2)(A), Lupin has committed an act of infringement of the '769 patent by submitting Lupin's ODEFSEY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ODEFSEY ANDA Product in the United States prior to the expiration of the '769 patent.

680. Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ODEFSEY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[27]

681. On information and belief, for example, Lupin's ODEFSEY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

682. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

683. Unless and until Lupin is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXVIII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Lupin's ODEFSEY ANDA Product

[27] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

684. Gilead realleges the foregoing paragraphs as if fully set forth herein.

685. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

686. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

687. Lupin has submitted an ANDA for a generic version of Gilead's ODEFSEY pharmaceutical product. According to Lupin's ODEFSEY Notice Letter, Lupin intends to manufacture, use, offer for sale, sell, and/or import Lupin's ODEFSEY ANDA Product within the United States.

688. While the FDA has not yet approved Lupin's ODEFSEY ANDA, Lupin has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Lupin's ODEFSEY ANDA Product.

689. Lupin's actions indicate that it does not intend to change its course of conduct.

690. On information and belief, upon FDA approval of Lupin's ODEFSEY ANDA, Lupin will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[28] by making, using, offering to sell, and/or selling Lupin's ODEFSEY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

691. On information and belief, for example, Lupin's ODEFSEY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition

[28] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

692. Lupin has actual knowledge of the '769 patent.

693. On information and belief, Lupin became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's ODEFSEY product.

694. On information and belief, Lupin's efforts to make, use, sell, offer for sell, and/or import its ODEFSEY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Lupin's ODEFSEY Notice Letter, which does not contest infringement of at least claim 1 of the '769 patent, except on the basis that the claim is allegedly invalid.

695. On information and belief, Lupin's ODEFSEY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Lupin in the United States by it or on its behalf.

696. On information and belief, Lupin's Proposed ODEFSEY Label will include directions and instructions that instruct physicians and healthcare providers to administer Lupin's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

697. On information and belief, physicians and healthcare providers will administer Lupin's ODEFSEY ANDA Product in the United States according to the directions and

instructions in Lupin's Proposed ODEFSEY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

698. On information and belief, at least through its Proposed ODEFSEY Label, Lupin will encourage physicians and healthcare providers to administer Lupin's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Lupin will know or should know that such conduct will occur.

699. On information and belief, Lupin will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

700. Through at least the foregoing actions, Lupin will actively induce the infringement of at least one claim of the '769 patent.

701. On information and belief, Lupin knows or should know that Lupin's ODEFSEY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Lupin's ODEFSEY ANDA Product is not suitable for substantial non-infringing use.

702. The commercial manufacture, use, sale, offer for sale, and/or importation of Lupin's ODEFSEY ANDA Product will contribute to the actual infringement of the '769 patent.

703. On information and belief, Lupin knows or should know that its offer for sale, sale and/or importation of its ODEFSEY ANDA Product will contribute to the actual infringement of the '769 patent.

704. Through at least the foregoing actions, Lupin will contribute to the infringement of at least one claim of the '769 patent.

705. On information and belief, if Lupin's ODEFSEY ANDA is approved by the FDA,

Lupin will make its ODEFSEY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

706. On information and belief, Lupin's ODEFSEY ANDA Product will not be materially changed by a subsequent process nor will Lupin's ODEFSEY ANDA Product become a trivial and nonessential component of another product.

707. Through at least the foregoing actions, Lupin will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

708. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Lupin's ODEFSEY ANDA Product by Lupin prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

709. The commercial manufacture, importation, use, sale, or offer for sale of Lupin's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

710. Unless and until Lupin is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNTS XXIX-XL AGAINST LAURUS LABS

VEMLIDY Counts

Count XXIX: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Laurus Labs's VEMLIDY ANDA Product

711. Gilead realleges the foregoing paragraphs as if fully set forth herein.

712. Pursuant to 35 U.S.C. § 271(e)(2)(A), Laurus Labs has committed an act of infringement of the '065 patent by submitting Laurus Labs's VEMLIDY ANDA to obtain approval

to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product in the United States prior to the expiration of the '065 patent.

713. Laurus Labs's commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[29]

714. On information and belief, for example, Laurus Labs's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

715. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

716. Unless and until Laurus Labs is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXX: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Laurus Labs's VEMLIDY ANDA Product

717. Gilead realleges the foregoing paragraphs as if fully set forth herein.

718. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

719. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

[29] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

720. Laurus Labs has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Laurus Labs's First VEMLIDY Notice Letter, Laurus Labs intends to manufacture, use, offer for sale, sell, and/or import Laurus Labs's VEMLIDY ANDA Product within the United States.

721. While the FDA has not yet approved Laurus Labs's VEMLIDY ANDA, Laurus Labs has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Laurus Labs's VEMLIDY ANDA Product.

722. Laurus Labs's actions indicate that it does not intend to change its course of conduct.

723. On information and belief, upon FDA approval of Laurus Labs's VEMLIDY ANDA, Laurus Labs will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[30] by making, using, offering to sell, and/or selling Laurus Labs's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

724. On information and belief, for example, Laurus Labs's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

725. Laurus Labs has actual knowledge of the '065 patent.

726. On information and belief, Laurus Labs became aware of the '065 patent no later

[30] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

727. On information and belief, Laurus Labs's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Laurus Labs's First VEMLIDY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

728. On information and belief, Laurus Labs's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Laurus Labs in the United States by it or on its behalf.

729. On information and belief, Laurus Labs's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Laurus Labs's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent.

730. On information and belief, physicians and healthcare providers will administer Laurus Labs's VEMLIDY ANDA Product in the United States according to the directions and instructions in Laurus Labs's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

731. On information and belief, at least through its Proposed VEMLIDY Label, Laurus Labs will encourage physicians and healthcare providers to administer Laurus Labs's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods

described/claimed in the ’065 patent, and Laurus Labs will know or should know that such conduct will occur.

732. On information and belief, Laurus Labs will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the ’065 patent.

733. Through at least the foregoing actions, Laurus Labs will actively induce the infringement of at least one claim of the ’065 patent.

734. On information and belief, Laurus Labs knows or should know that Laurus Labs’s VEMLIDY ANDA Product will be especially made or adapted for use in infringing the ’065 patent and that Laurus Labs’s VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

735. The commercial manufacture, use, sale, offer for sale, and/or importation of Laurus Labs’s VEMLIDY ANDA Product will contribute to the actual infringement of the ’065 patent.

736. On information and belief, Laurus Labs knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the ’065 patent.

737. Through at least the foregoing actions, Laurus Labs will contribute to the infringement of at least one claim of the ’065 patent.

738. On information and belief, if Laurus Labs’s VEMLIDY ANDA is approved by the FDA, Laurus Labs will make its VEMLIDY ANDA Product using a process covered by one or more claims of the ’065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

739. On information and belief, Laurus Labs’s VEMLIDY ANDA Product will not be

materially changed by a subsequent process nor will Laurus Labs's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

740. Through at least the foregoing actions, Laurus Labs will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

741. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product by Laurus Labs prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

742. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

743. Unless and until Laurus Labs is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXXI: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Laurus Labs's VEMLIDY ANDA Product

744. Gilead realleges the foregoing paragraphs as if fully set forth herein.

745. Pursuant to 35 U.S.C. § 271(e)(2)(A), Laurus Labs has committed an act of infringement of the '769 patent by submitting Laurus Labs's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product in the United States prior to the expiration of the '769 patent.

746. Laurus Labs's commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product prior to the expiration of the '769 patent, and its

inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[31]

747. On information and belief, for example, Laurus Labs's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

748. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

749. Unless and until Laurus Labs is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXXII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Laurus Labs's VEMLIDY ANDA Product

750. Gilead realleges the foregoing paragraphs as if fully set forth herein.

751. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

752. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

753. Laurus Labs has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Laurus Labs's First VEMLIDY Notice Letter, Laurus Labs

[31] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

intends to manufacture, use, offer for sale, sell, and/or import Laurus Labs's VEMLIDY ANDA Product within the United States.

754. While the FDA has not yet approved Laurus Labs's VEMLIDY ANDA, Laurus Labs has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Laurus Labs's VEMLIDY ANDA Product.

755. Laurus Labs's actions indicate that it does not intend to change its course of conduct.

756. On information and belief, upon FDA approval of Laurus Labs's VEMLIDY ANDA, Laurus Labs will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[32] by making, using, offering to sell, and/or selling Laurus Labs's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

757. On information and belief, for example, Laurus Labs's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

758. Laurus Labs has actual knowledge of the '769 patent.

[32] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

759. On information and belief, Laurus Labs became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

760. On information and belief, Laurus Labs's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Laurus Labs's First VEMLIDY Notice Letter, which does not contest infringement of at least claim 1 of the '769 patent, except on the basis that the claim is allegedly invalid.

761. On information and belief, Laurus Labs's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Laurus Labs in the United States by it or on its behalf.

762. On information and belief, Laurus Labs's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Laurus Labs's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent.

763. On information and belief, physicians and healthcare providers will administer Laurus Labs's VEMLIDY ANDA Product in the United States according to the directions and instructions in Laurus Labs's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

764. On information and belief, at least through its Proposed VEMLIDY Label, Laurus Labs will encourage physicians and healthcare providers to administer Laurus Labs's VEMLIDY

ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent, and Laurus Labs will know or should know that such conduct will occur.

765. On information and belief, Laurus Labs will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

766. Through at least the foregoing actions, Laurus Labs will actively induce the infringement of at least one claim of the '769 patent.

767. On information and belief, Laurus Labs knows or should know that Laurus Labs's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Laurus Labs's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

768. The commercial manufacture, use, sale, offer for sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

769. On information and belief, Laurus Labs knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

770. Through at least the foregoing actions, Laurus Labs will contribute to the infringement of at least one claim of the '769 patent.

771. On information and belief, if Laurus Labs's VEMLIDY ANDA is approved by the FDA, Laurus Labs will make its VEMLIDY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

772. On information and belief, Laurus Labs's VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Laurus Labs's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

773. Through at least the foregoing actions, Laurus Labs will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

774. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product by Laurus Labs prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

775. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

776. Unless and until Laurus Labs is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

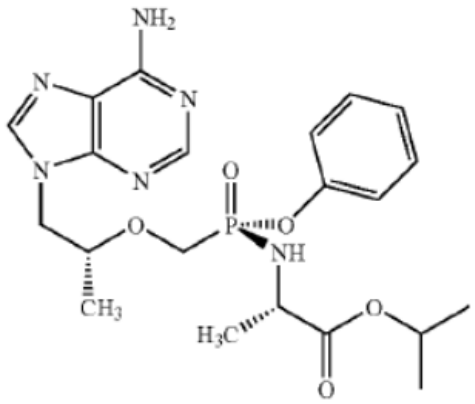
Count XXXIII: Infringement of the '791 Patent under 35 U.S.C. § 271(e)(2) by Laurus Labs's VEMLIDY ANDA Product

777. Gilead realleges the foregoing paragraphs as if fully set forth herein.

778. Pursuant to 35 U.S.C. § 271(e)(2)(A), Laurus Labs has committed an act of infringement of the '791 patent by submitting Laurus Labs's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product in the United States prior to the expiration of the '791 patent.

779. Laurus Labs's commercial manufacture, use, offer for sale, sale, and/or importation of its VEMLIDY ANDA Product prior to the expiration of the '791 patent would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[33]

780. On information and belief, for example, Laurus Labs's VEMLIDY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

781. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

782. Unless and until Laurus Labs is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXXIV: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Laurus Labs's VEMLIDY ANDA Product

783. Gilead realleges the foregoing paragraphs as if fully set forth herein.

[33] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

784. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

785. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

786. Laurus has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Laurus Labs's Second VEMLIDY Notice Letter, Laurus Labs intends to manufacture, use, offer for sale, sell, and/or import its VEMLIDY ANDA Product within the United States.

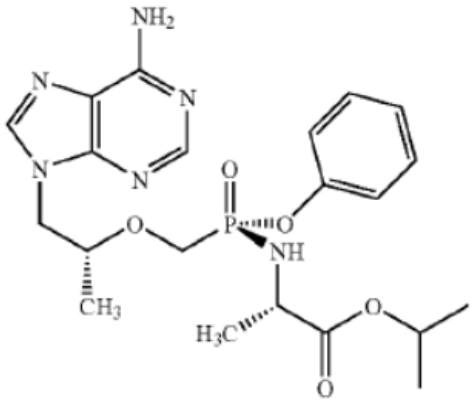
787. While the FDA has not yet approved Laurus Labs's VEMLIDY ANDA, Laurus has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its VEMLIDY ANDA Product.

788. Laurus Labs's actions indicate that it does not intend to change its course of conduct.

789. On information and belief, upon FDA approval of Laurus Labs's VEMLIDY ANDA, Laurus will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[34] by making, using, offering to sell, and/or selling Laurus Labs's VEMLIDY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

790. On information and belief, for example, Laurus Labs's VEMLIDY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:

[34] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

791. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's VEMLIDY ANDA Product by Laurus prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

792. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

793. Unless and until Laurus Labs is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

DESCOVY Counts

Count XXXV: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Laurus Labs's DESCOVY ANDA Product

794. Gilead realleges the foregoing paragraphs as if fully set forth herein.

795. Pursuant to 35 U.S.C. § 271(e)(2)(A), Laurus Labs has committed an act of infringement of the '065 patent by submitting Laurus Labs's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of

Laurus Labs's DESCOVY ANDA Product in the United States prior to the expiration of the '065 patent.

796. Laurus Labs's commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's DESCOVY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[35]

797. On information and belief, for example, Laurus Labs's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

798. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

799. Unless and until Laurus Labs is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXXVI: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Laurus Labs's DESCOVY ANDA Product

800. Gilead realleges the foregoing paragraphs as if fully set forth herein.

801. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

802. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

[35] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

803. Laurus Labs has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Laurus Labs's First DESCOVY Notice Letter, Laurus Labs intends to manufacture, use, offer for sale, sell, and/or import Laurus Labs's DESCOVY ANDA Product within the United States.

804. While the FDA has not yet approved Laurus Labs's DESCOVY ANDA, Laurus Labs has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Laurus Labs's DESCOVY ANDA Product.

805. Laurus Labs's actions indicate that it does not intend to change its course of conduct.

806. On information and belief, upon FDA approval of Laurus Labs's DESCOVY ANDA, Laurus Labs will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[36] by making, using, offering to sell, and/or selling Laurus Labs's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

807. On information and belief, for example, Laurus Labs's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

808. Laurus Labs has actual knowledge of the '065 patent.

809. On information and belief, Laurus Labs became aware of the '065 patent no later

[36] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

810. On information and belief, Laurus Labs's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Laurus Labs's First DESCOVY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

811. On information and belief, Laurus Labs's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Laurus Labs in the United States by it or on its behalf.

812. On information and belief, Laurus Labs's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Laurus Labs's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent.

813. On information and belief, physicians and healthcare providers will administer Laurus Labs's DESCOVY ANDA Product in the United States according to the directions and instructions in Laurus Labs's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

814. On information and belief, at least through its Proposed DESCOVY Label, Laurus Labs will encourage physicians and healthcare providers to administer Laurus Labs's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods

described/claimed in the '065 patent, and Laurus Labs will know or should know that such conduct will occur.

815. On information and belief, Laurus Labs will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

816. Through at least the foregoing actions, Laurus Labs will actively induce the infringement of at least one claim of the '065 patent.

817. On information and belief, Laurus Labs knows or should know that Laurus Labs's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '065 patent and that Laurus Labs's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

818. The commercial manufacture, use, sale, offer for sale, and/or importation of Laurus Labs's DESCOVY ANDA Product will contribute to the actual infringement of the '065 patent.

819. On information and belief, Laurus Labs knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '065 patent.

820. Through at least the foregoing actions, Laurus Labs will contribute to the infringement of at least one claim of the '065 patent.

821. On information and belief, if Laurus Labs's DESCOVY ANDA is approved by the FDA, Laurus Labs will make its DESCOVY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

822. On information and belief, Laurus Labs's DESCOVY ANDA Product will not be

materially changed by a subsequent process nor will Laurus Labs's DESCOVY ANDA Product become a trivial and nonessential component of another product.

823. Through at least the foregoing actions, Laurus Labs will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

824. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's DESCOVY ANDA Product by Laurus Labs prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

825. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

826. Unless and until Laurus Labs is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXXVII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Laurus Labs's DESCOVY ANDA Product

827. Gilead realleges the foregoing paragraphs as if fully set forth herein.

828. Pursuant to 35 U.S.C. § 271(e)(2)(A), Laurus Labs has committed an act of infringement of the '769 patent by submitting Laurus Labs's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's DESCOVY ANDA Product in the United States prior to the expiration of the '769 patent.

829. Laurus Labs's commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's DESCOVY ANDA Product prior to the expiration of the '769 patent, and its

inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[37]

830. On information and belief, for example, Laurus Labs's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

831. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

832. Unless and until Laurus Labs is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XXXVIII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Laurus Labs's DESCOVY ANDA Product

833. Gilead realleges the foregoing paragraphs as if fully set forth herein.

834. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

835. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

836. Laurus Labs has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Laurus Labs's First DESCOVY Notice Letter, Laurus Labs

[37] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

intends to manufacture, use, offer for sale, sell, and/or import Laurus Labs's DESCOVY ANDA Product within the United States.

837. While the FDA has not yet approved Laurus Labs's DESCOVY ANDA, Laurus Labs has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Laurus Labs's DESCOVY ANDA Product.

838. Laurus Labs's actions indicate that it does not intend to change its course of conduct.

839. On information and belief, upon FDA approval of Laurus Labs's DESCOVY ANDA, Laurus Labs will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[38] by making, using, offering to sell, and/or selling Laurus Labs's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

840. On information and belief, for example, Laurus Labs's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

841. Laurus Labs has actual knowledge of the '769 patent.

[38] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

842. On information and belief, Laurus Labs became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

843. On information and belief, Laurus Labs's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Laurus Labs's First DESCOVY Notice Letter, which does not contest infringement of at least claim 1 of the '769 patent, except on the basis that the claim is allegedly invalid.

844. On information and belief, Laurus Labs's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Laurus Labs in the United States by it or on its behalf.

845. On information and belief, Laurus Labs's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Laurus Labs's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

846. On information and belief, physicians and healthcare providers will administer Laurus Labs's DESCOVY ANDA Product in the United States according to the directions and instructions in Laurus Labs's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

847. On information and belief, at least through its Proposed DESCOVY Label, Laurus Labs will encourage physicians and healthcare providers to administer Laurus Labs's DESCOVY

ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Laurus Labs will know or should know that such conduct will occur.

848. On information and belief, Laurus Labs will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

849. Through at least the foregoing actions, Laurus Labs will actively induce the infringement of at least one claim of the '769 patent.

850. On information and belief, Laurus Labs knows or should know that Laurus Labs's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Laurus Labs's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

851. The commercial manufacture, use, sale, offer for sale, and/or importation of Laurus Labs's DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

852. On information and belief, Laurus Labs knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

853. Through at least the foregoing actions, Laurus Labs will contribute to the infringement of at least one claim of the '769 patent.

854. On information and belief, if Laurus Labs's DESCOVY ANDA is approved by the FDA, Laurus Labs will make its DESCOVY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

855. On information and belief, Laurus Labs's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Laurus Labs's DESCOVY ANDA Product become a trivial and nonessential component of another product.

856. Through at least the foregoing actions, Laurus Labs will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

857. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's DESCOVY ANDA Product by Laurus Labs prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

858. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

859. Unless and until Laurus Labs is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

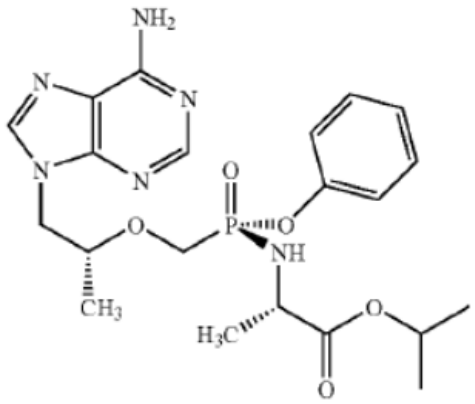
Count XXXIX: Infringement of the '791 Patent under 35 U.S.C. § 271(e)(2) by Laurus Labs's DESCOVY ANDA Product

860. Gilead realleges the foregoing paragraphs as if fully set forth herein.

861. Pursuant to 35 U.S.C. § 271(e)(2)(A), Laurus Labs has committed an act of infringement of the '791 patent by submitting Laurus Labs's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's DESCOVY ANDA Product in the United States prior to the expiration of the '791 patent.

862. Laurus Labs's commercial manufacture, use, offer for sale, sale, and/or importation of its DESCOVY ANDA Product prior to the expiration of the '791 patent would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[39]

863. On information and belief, for example, Laurus Labs's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

864. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

865. Unless and until Laurus Labs is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XL: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Laurus Labs's DESCOVY ANDA Product

866. Gilead realleges the foregoing paragraphs as if fully set forth herein.

[39] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

867. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

868. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

869. Laurus has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Laurus Labs's Second DESCOVY Notice Letter, Laurus Labs intends to manufacture, use, offer for sale, sell, and/or import its DESCOVY ANDA Product within the United States.

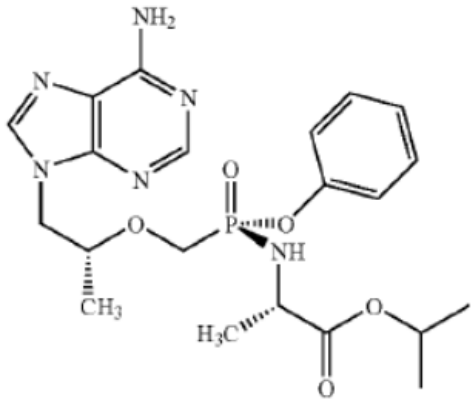
870. While the FDA has not yet approved Laurus Labs's DESCOVY ANDA, Laurus has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its DESCOVY ANDA Product.

871. Laurus Labs's actions indicate that it does not intend to change its course of conduct.

872. On information and belief, upon FDA approval of Laurus Labs's DESCOVY ANDA, Laurus will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[40] by making, using, offering to sell, and/or selling Laurus Labs's DESCOVY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

873. On information and belief, for example, Laurus Labs's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:

[40] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

874. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Laurus Labs's DESCOVY ANDA Product by Laurus prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

875. The commercial manufacture, importation, use, sale, or offer for sale of Laurus Labs's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

876. Unless and until Laurus Labs is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNTS XLI-XLIV AGAINST SHILPA

VEMLIDY Counts

Count XLI: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Shilpa's VEMLIDY ANDA Product

877. Gilead realleges the foregoing paragraphs as if fully set forth herein.

878. Pursuant to 35 U.S.C. § 271(e)(2)(A), Shilpa has committed an act of infringement of the '065 patent by submitting Shilpa's VEMLIDY ANDA to obtain approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of Shilpa's VEMLIDY ANDA Product in the United States prior to the expiration of the '065 patent.

879. Shilpa's commercial manufacture, use, offer for sale, sale, and/or importation of Shilpa's VEMLIDY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[41]

880. On information and belief, for example, Shilpa's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

881. The commercial manufacture, importation, use, sale, or offer for sale of Shilpa's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

882. Unless and until Shilpa is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XLII: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Shilpa's VEMLIDY ANDA Product

883. Gilead realleges the foregoing paragraphs as if fully set forth herein.

884. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

885. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

[41] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

886. Shilpa has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Shilpa's VEMLIDY Notice Letter, Shilpa intends to manufacture, use, offer for sale, sell, and/or import Shilpa's VEMLIDY ANDA Product within the United States.

887. While the FDA has not yet approved Shilpa's VEMLIDY ANDA, Shilpa has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Shilpa's VEMLIDY ANDA Product.

888. Shilpa's actions indicate that it does not intend to change its course of conduct.

889. On information and belief, upon FDA approval of Shilpa's VEMLIDY ANDA, Shilpa will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[42] by making, using, offering to sell, and/or selling Shilpa's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

890. On information and belief, for example, Shilpa's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

891. Shilpa has actual knowledge of the '065 patent.

892. On information and belief, Shilpa became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

[42] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

893. On information and belief, Shilpa's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Shilpa's VEMLIDY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

894. On information and belief, Shilpa's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Shilpa in the United States by it or on its behalf.

895. On information and belief, Shilpa's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Shilpa's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent.

896. On information and belief, physicians and healthcare providers will administer Shilpa's VEMLIDY ANDA Product in the United States according to the directions and instructions in Shilpa's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

897. On information and belief, at least through its Proposed VEMLIDY Label, Shilpa will encourage physicians and healthcare providers to administer Shilpa's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent, and Shilpa will know or should know that such conduct will occur.

898. On information and belief, Shilpa will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the ’065 patent.

899. Through at least the foregoing actions, Shilpa will actively induce the infringement of at least one claim of the ’065 patent.

900. On information and belief, Shilpa knows or should know that Shilpa’s VEMLIDY ANDA Product will be especially made or adapted for use in infringing the ’065 patent and that Shilpa’s VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

901. The commercial manufacture, use, sale, offer for sale, and/or importation of Shilpa’s VEMLIDY ANDA Product will contribute to the actual infringement of the ’065 patent.

902. On information and belief, Shilpa knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the ’065 patent.

903. Through at least the foregoing actions, Shilpa will contribute to the infringement of at least one claim of the ’065 patent.

904. On information and belief, if Shilpa’s VEMLIDY ANDA is approved by the FDA, Shilpa will make its VEMLIDY ANDA Product using a process covered by one or more claims of the ’065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

905. On information and belief, Shilpa’s VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Shilpa’s VEMLIDY ANDA Product become a trivial and nonessential component of another product.

906. Through at least the foregoing actions, Shilpa will infringe at least one claim of the

'065 patent under 35 U.S.C. § 271(g).

907. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Shilpa's VEMLIDY ANDA Product by Shilpa prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

908. The commercial manufacture, importation, use, sale, or offer for sale of Shilpa's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

909. Unless and until Shilpa is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XLIII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Shilpa's VEMLIDY ANDA Product

910. Gilead realleges the foregoing paragraphs as if fully set forth herein.

911. Pursuant to 35 U.S.C. § 271(e)(2)(A), Shilpa has committed an act of infringement of the '769 patent by submitting Shilpa's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Shilpa's VEMLIDY ANDA Product in the United States prior to the expiration of the '769 patent.

912. Shilpa's commercial manufacture, use, offer for sale, sale, and/or importation of Shilpa's VEMLIDY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[43]

[43] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

913. On information and belief, for example, Shilpa's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

914. The commercial manufacture, importation, use, sale, or offer for sale of Shilpa's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

915. Unless and until Shilpa is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XLIV: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Shilpa's VEMLIDY ANDA Product

916. Gilead realleges the foregoing paragraphs as if fully set forth herein.

917. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

918. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

919. Shilpa has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Shilpa's VEMLIDY Notice Letter, Shilpa intends to manufacture, use, offer for sale, sell, and/or import Shilpa's VEMLIDY ANDA Product within the United States.

920. While the FDA has not yet approved Shilpa's VEMLIDY ANDA, Shilpa has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Shilpa's VEMLIDY ANDA Product.

921. Shilpa's actions indicate that it does not intend to change its course of conduct.

922. On information and belief, upon FDA approval of Shilpa's VEMLIDY ANDA, Shilpa will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[44] by making, using, offering to sell, and/or selling Shilpa's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

923. On information and belief, for example, Shilpa's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

924. Shilpa has actual knowledge of the '769 patent.

925. On information and belief, Shilpa became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

926. On information and belief, Shilpa's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Shilpa's VEMLIDY Notice Letter, which

[44] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

does not contest infringement of at least claim 1 of the '769 patent, except on the basis that the claim is allegedly invalid.

927. On information and belief, Shilpa's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Shilpa in the United States by it or on its behalf.

928. On information and belief, Shilpa's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Shilpa's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent.

929. On information and belief, physicians and healthcare providers will administer Shilpa's VEMLIDY ANDA Product in the United States according to the directions and instructions in Shilpa's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

930. On information and belief, at least through its Proposed VEMLIDY Label, Shilpa will encourage physicians and healthcare providers to administer Shilpa's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent, and Shilpa will know or should know that such conduct will occur.

931. On information and belief, Shilpa will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

932. Through at least the foregoing actions, Shilpa will actively induce the infringement of at least one claim of the '769 patent.

933. On information and belief, Shilpa knows or should know that Shilpa's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Shilpa's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

934. The commercial manufacture, use, sale, offer for sale, and/or importation of Shilpa's VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

935. On information and belief, Shilpa knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

936. Through at least the foregoing actions, Shilpa will contribute to the infringement of at least one claim of the '769 patent.

937. On information and belief, if Shilpa's VEMLIDY ANDA is approved by the FDA, Shilpa will make its VEMLIDY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

938. On information and belief, Shilpa's VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Shilpa's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

939. Through at least the foregoing actions, Shilpa will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

940. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Shilpa's VEMLIDY ANDA Product by Shilpa prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

941. The commercial manufacture, importation, use, sale, or offer for sale of Shilpa's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

942. Unless and until Shilpa is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNTS XLV-XLVIII AGAINST SUNSHINE LAKE

VEMLIDY Counts

Count XLV: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Sunshine Lake's VEMLIDY ANDA Product

943. Gilead realleges the foregoing paragraphs as if fully set forth herein.

944. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sunshine Lake has committed an act of infringement of the '065 patent by submitting Sunshine Lake's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sunshine Lake's VEMLIDY ANDA Product in the United States prior to the expiration of the '065 patent.

945. Sunshine Lake's commercial manufacture, use, offer for sale, sale, and/or importation of Sunshine Lake's VEMLIDY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[45]

946. On information and belief, for example, Sunshine Lake's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

[45] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

947. The commercial manufacture, importation, use, sale, or offer for sale of Sunshine Lake's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

948. Unless and until Sunshine Lake is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XLVI: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Sunshine Lake's VEMLIDY ANDA Product

949. Gilead realleges the foregoing paragraphs as if fully set forth herein.

950. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

951. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

952. Sunshine Lake has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Sunshine Lake's VEMLIDY Notice Letter, Sunshine Lake intends to manufacture, use, offer for sale, sell, and/or import Sunshine Lake's VEMLIDY ANDA Product within the United States.

953. While the FDA has not yet approved Sunshine Lake's VEMLIDY ANDA, Sunshine Lake has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Sunshine Lake's VEMLIDY ANDA Product.

954. Sunshine Lake's actions indicate that it does not intend to change its course of conduct.

955. On information and belief, upon FDA approval of Sunshine Lake's VEMLIDY ANDA, Sunshine Lake will infringe one or more claims of the '065 patent, either literally or under

the doctrine of equivalents, including but not limited to claim 1,[46] by making, using, offering to sell, and/or selling Sunshine Lake's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

956. On information and belief, for example, Sunshine Lake's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

957. Sunshine Lake has actual knowledge of the '065 patent.

958. On information and belief, Sunshine Lake became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

959. On information and belief, Sunshine Lake's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Sunshine Lake's VEMLIDY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

[46] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

960. On information and belief, Sunshine Lake's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Sunshine Lake in the United States by it or on its behalf.

961. On information and belief, Sunshine Lake's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Sunshine Lake's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent.

962. On information and belief, physicians and healthcare providers will administer Sunshine Lake's VEMLIDY ANDA Product in the United States according to the directions and instructions in Sunshine Lake's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

963. On information and belief, at least through its Proposed VEMLIDY Label, Sunshine Lake will encourage physicians and healthcare providers to administer Sunshine Lake's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent, and Sunshine Lake will know or should know that such conduct will occur.

964. On information and belief, Sunshine Lake will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

965. Through at least the foregoing actions, Sunshine Lake will actively induce the infringement of at least one claim of the '065 patent.

966. On information and belief, Sunshine Lake knows or should know that Sunshine Lake's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the

'065 patent and that Sunshine Lake's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

967. The commercial manufacture, use, sale, offer for sale, and/or importation of Sunshine Lake's VEMLIDY ANDA Product will contribute to the actual infringement of the '065 patent.

968. On information and belief, Sunshine Lake knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '065 patent.

969. Through at least the foregoing actions, Sunshine Lake will contribute to the infringement of at least one claim of the '065 patent.

970. On information and belief, if Sunshine Lake's VEMLIDY ANDA is approved by the FDA, Sunshine Lake will make its VEMLIDY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

971. On information and belief, Sunshine Lake's VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Sunshine Lake's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

972. Through at least the foregoing actions, Sunshine Lake will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

973. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Sunshine Lake's VEMLIDY ANDA Product by Sunshine Lake prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

974. The commercial manufacture, importation, use, sale, or offer for sale of Sunshine Lake's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

975. Unless and until Sunshine Lake is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XLVII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Sunshine Lake's VEMLIDY ANDA Product

976. Gilead realleges the foregoing paragraphs as if fully set forth herein.

977. Pursuant to 35 U.S.C. § 271(e)(2)(A), Sunshine Lake has committed an act of infringement of the '769 patent by submitting Sunshine Lake's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sunshine Lake's VEMLIDY ANDA Product in the United States prior to the expiration of the '769 patent.

978. Sunshine Lake's commercial manufacture, use, offer for sale, sale, and/or importation of Sunshine Lake's VEMLIDY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[47]

979. On information and belief, for example, Sunshine Lake's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

[47] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

980. The commercial manufacture, importation, use, sale, or offer for sale of Sunshine Lake's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

981. Unless and until Sunshine Lake is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count XLVIII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Sunshine Lake's VEMLIDY ANDA Product

982. Gilead realleges the foregoing paragraphs as if fully set forth herein.

983. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

984. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

985. Sunshine Lake has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Sunshine Lake's VEMLIDY Notice Letter, Sunshine Lake intends to manufacture, use, offer for sale, sell, and/or import Sunshine Lake's VEMLIDY ANDA Product within the United States.

986. While the FDA has not yet approved Sunshine Lake's VEMLIDY ANDA, Sunshine Lake has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Sunshine Lake's VEMLIDY ANDA Product.

987. Sunshine Lake's actions indicate that it does not intend to change its course of conduct.

988. On information and belief, upon FDA approval of Sunshine Lake's VEMLIDY ANDA, Sunshine Lake will infringe one or more claims of the '769 patent, either literally or under

the doctrine of equivalents, including but not limited to claim 1,[48] by making, using, offering to sell, and/or selling Sunshine Lake's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

989. On information and belief, for example, Sunshine Lake's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

990. Sunshine Lake has actual knowledge of the '769 patent.

991. On information and belief, Sunshine Lake became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

992. On information and belief, Sunshine Lake's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Sunshine Lake's VEMLIDY Notice Letter, which does not contest infringement of at least claim 1 of the '769 patent, except on the basis that the claim is allegedly invalid.

[48] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

993. On information and belief, Sunshine Lake's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Sunshine Lake in the United States by it or on its behalf.

994. On information and belief, Sunshine Lake's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Sunshine Lake's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent.

995. On information and belief, physicians and healthcare providers will administer Sunshine Lake's VEMLIDY ANDA Product in the United States according to the directions and instructions in Sunshine Lake's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

996. On information and belief, at least through its Proposed VEMLIDY Label, Sunshine Lake will encourage physicians and healthcare providers to administer Sunshine Lake's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent, and Sunshine Lake will know or should know that such conduct will occur.

997. On information and belief, Sunshine Lake will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

998. Through at least the foregoing actions, Sunshine Lake will actively induce the infringement of at least one claim of the '769 patent.

999. On information and belief, Sunshine Lake knows or should know that Sunshine Lake's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the

'769 patent and that Sunshine Lake's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

1000. The commercial manufacture, use, sale, offer for sale, and/or importation of Sunshine Lake's VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

1001. On information and belief, Sunshine Lake knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

1002. Through at least the foregoing actions, Sunshine Lake will contribute to the infringement of at least one claim of the '769 patent.

1003. On information and belief, if Sunshine Lake's VEMLIDY ANDA is approved by the FDA, Sunshine Lake will make its VEMLIDY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1004. On information and belief, Sunshine Lake's VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Sunshine Lake's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

1005. Through at least the foregoing actions, Sunshine Lake will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

1006. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Sunshine Lake's VEMLIDY ANDA Product by Sunshine Lake prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

1007. The commercial manufacture, importation, use, sale, or offer for sale of Sunshine Lake's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1008. Unless and until Sunshine Lake is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNTS XLIX-LIV AGAINST NATCO

DESCOVY Counts

Count XLIX: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Natco's DESCOVY ANDA Product

1009. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1010. Pursuant to 35 U.S.C. § 271(e)(2)(A), Natco has committed an act of infringement of the '065 patent by submitting Natco's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Natco's DESCOVY ANDA Product in the United States prior to the expiration of the '065 patent.

1011. Natco's commercial manufacture, use, offer for sale, sale, and/or importation of Natco's DESCOVY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[49]

1012. On information and belief, for example, Natco's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1013. The commercial manufacture, importation, use, sale, or offer for sale of Natco's

[49] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1014. Unless and until Natco is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count L: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Natco's DESCOVY ANDA Product

1015. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1016. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1017. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1018. Natco has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Natco's First DESCOVY Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import Natco's DESCOVY ANDA Product within the United States.

1019. While the FDA has not yet approved Natco's DESCOVY ANDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Natco's DESCOVY ANDA Product.

1020. Natco's actions indicate that it does not intend to change its course of conduct.

1021. On information and belief, upon FDA approval of Natco's DESCOVY ANDA, Natco will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[50] by making, using, offering to sell, and/or selling

[50] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

Natco's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1022. On information and belief, for example, Natco's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1023. Natco has actual knowledge of the '065 patent.

1024. On information and belief, Natco became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

1025. On information and belief, Natco's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Natco's First DESCOVY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

1026. On information and belief, Natco's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Natco in the United States by it or on its behalf.

1027. On information and belief, Natco's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Natco's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with

the methods described/claimed in the ’065 patent.

1028. On information and belief, physicians and healthcare providers will administer Natco’s DESCOVY ANDA Product in the United States according to the directions and instructions in Natco’s Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the ’065 patent.

1029. On information and belief, at least through its Proposed DESCOVY Label, Natco will encourage physicians and healthcare providers to administer Natco’s DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the ’065 patent, and Natco will know or should know that such conduct will occur.

1030. On information and belief, Natco will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the ’065 patent.

1031. Through at least the foregoing actions, Natco will actively induce the infringement of at least one claim of the ’065 patent.

1032. On information and belief, Natco knows or should know that Natco’s DESCOVY ANDA Product will be especially made or adapted for use in infringing the ’065 patent and that Natco’s DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1033. The commercial manufacture, use, sale, offer for sale, and/or importation of Natco’s DESCOVY ANDA Product will contribute to the actual infringement of the ’065 patent.

1034. On information and belief, Natco knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the ’065 patent.

1035. Through at least the foregoing actions, Natco will contribute to the infringement of at least one claim of the ’065 patent.

1036. On information and belief, if Natco’s DESCOVY ANDA is approved by the FDA, Natco will make its DESCOVY ANDA Product using a process covered by one or more claims of the ’065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1037. On information and belief, Natco’s DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Natco’s DESCOVY ANDA Product become a trivial and nonessential component of another product.

1038. Through at least the foregoing actions, Natco will infringe at least one claim of the ’065 patent under 35 U.S.C. § 271(g).

1039. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Natco’s DESCOVY ANDA Product by Natco prior to the expiration of the ’065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’065 patent.

1040. The commercial manufacture, importation, use, sale, or offer for sale of Natco’s DESCOVY ANDA Product in violation of Gilead’s patent rights will cause harm to Gilead for which damages are inadequate.

1041. Unless and until Natco is enjoined from infringing the ’065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LI: Infringement of the ’769 Patent under 35 U.S.C. § 271(e)(2) by Natco’s DESCOVY ANDA Product

1042. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1043. Pursuant to 35 U.S.C. § 271(e)(2)(A), Natco has committed an act of infringement of the '769 patent by submitting Natco's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Natco's DESCOVY ANDA Product in the United States prior to the expiration of the '769 patent.

1044. Natco's commercial manufacture, use, offer for sale, sale, and/or importation of Natco's DESCOVY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[51]

1045. On information and belief, for example, Natco's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1046. The commercial manufacture, importation, use, sale, or offer for sale of Natco's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1047. Unless and until Natco is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Natco's DESCOVY ANDA Product

1048. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1049. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[51] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

1050. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1051. Natco has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Natco's First DESCOVY Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import Natco's DESCOVY ANDA Product within the United States.

1052. While the FDA has not yet approved Natco's DESCOVY ANDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Natco's DESCOVY ANDA Product.

1053. Natco's actions indicate that it does not intend to change its course of conduct.

1054. On information and belief, upon FDA approval of Natco's DESCOVY ANDA, Natco will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[52] by making, using, offering to sell, and/or selling Natco's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1055. On information and belief, for example, Natco's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls

[52] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1056. Natco has actual knowledge of the '769 patent.

1057. On information and belief, Natco became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

1058. On information and belief, Natco's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Natco's First DESCOVY Notice Letter, which does not contest infringement of at least claim 1 of the '769 patent, except on the basis that the claim is allegedly invalid.

1059. On information and belief, Natco's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Natco in the United States by it or on its behalf.

1060. On information and belief, Natco's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Natco's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

1061. On information and belief, physicians and healthcare providers will administer Natco's DESCOVY ANDA Product in the United States according to the directions and instructions in Natco's Proposed DESCOVY Label, and such administration will constitute direct

infringement of at least one claim of the '769 patent.

1062. On information and belief, at least through its Proposed DESCOVY Label, Natco will encourage physicians and healthcare providers to administer Natco's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Natco will know or should know that such conduct will occur.

1063. On information and belief, Natco will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

1064. Through at least the foregoing actions, Natco will actively induce the infringement of at least one claim of the '769 patent.

1065. On information and belief, Natco knows or should know that Natco's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Natco's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1066. The commercial manufacture, use, sale, offer for sale, and/or importation of Natco's DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

1067. On information and belief, Natco knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

1068. Through at least the foregoing actions, Natco will contribute to the infringement of at least one claim of the '769 patent.

1069. On information and belief, if Natco's DESCOVY ANDA is approved by the FDA, Natco will make its DESCOVY ANDA Product using a process covered by one or more claims of

the ’769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1070. On information and belief, Natco’s DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Natco’s DESCOVY ANDA Product become a trivial and nonessential component of another product.

1071. Through at least the foregoing actions, Natco will infringe at least one claim of the ’769 patent under 35 U.S.C. § 271(g).

1072. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Natco’s DESCOVY ANDA Product by Natco prior to the expiration of the ’769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’769 patent.

1073. The commercial manufacture, importation, use, sale, or offer for sale of Natco’s DESCOVY ANDA Product in violation of Gilead’s patent rights will cause harm to Gilead for which damages are inadequate.

1074. Unless and until Natco is enjoined from infringing the ’769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

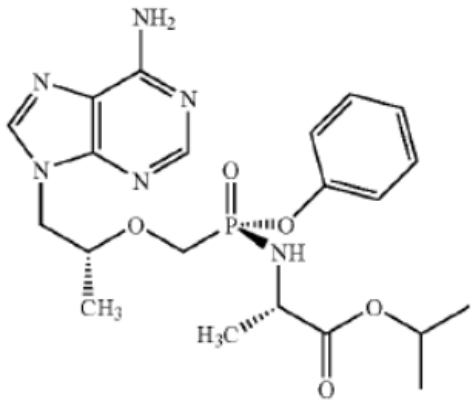
Count LIII: Infringement of the ’791 Patent under 35 U.S.C. § 271(e)(2) by Natco’s DESCOVY ANDA Product

1075. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1076. Pursuant to 35 U.S.C. § 271(e)(2)(A), Natco has committed an act of infringement of the ’791 patent by submitting Natco’s DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Natco’s DESCOVY ANDA Product in the United States prior to the expiration of the ’791 patent.

1077. Natco's commercial manufacture, use, offer for sale, sale, and/or importation of its DESCOVY ANDA Product prior to the expiration of the '791 patent would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[53]

1078. On information and belief, for example, Natco's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1079. The commercial manufacture, importation, use, sale, or offer for sale of Natco's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1080. Unless and until Natco is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LIV: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Natco's DESCOVY ANDA Product

1081. Gilead realleges the foregoing paragraphs as if fully set forth herein.

[53] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

1082. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1083. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1084. Natco has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Natco's Third DESCOVY Notice Letter, Natco intends to manufacture, use, offer for sale, sell, and/or import its DESCOVY ANDA Product within the United States.

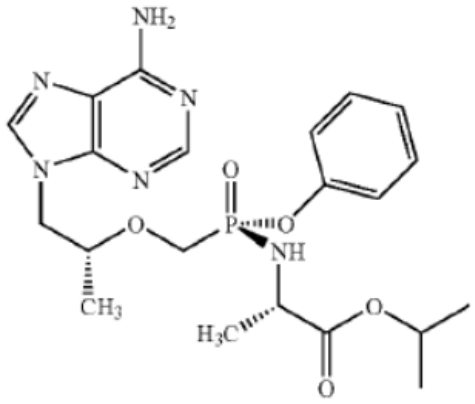
1085. While the FDA has not yet approved Natco's DESCOVY ANDA, Natco has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its DESCOVY ANDA Product.

1086. Natco's actions indicate that it does not intend to change its course of conduct.

1087. On information and belief, upon FDA approval of Natco's DESCOVY ANDA, Natco will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[54] by making, using, offering to sell, and/or selling Natco's DESCOVY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

1088. On information and belief, for example, Natco's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:

[54] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1089. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Natco's DESCOVY ANDA Product by Natco prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

1090. The commercial manufacture, importation, use, sale, or offer for sale of Natco's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1091. Unless and until Natco is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNTS LV-LXX AGAINST CIPLA

DESCOVY Counts

Count LV: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Cipla's DESCOVY ANDA Product

1092. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1093. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cipla has committed an act of infringement of the '065 patent by submitting Cipla's DESCOVY ANDA to obtain approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product in the United States prior to the expiration of the '065 patent.

1094. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[55]

1095. On information and belief, for example, Cipla's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1096. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1097. Unless and until Cipla is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LVI: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Cipla's DESCOVY ANDA Product

1098. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1099. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1100. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

[55] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

1101. Cipla has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Cipla's DESCOVY Notice Letter, Cipla intends to manufacture, use, offer for sale, sell, and/or import Cipla's DESCOVY ANDA Product within the United States.

1102. While the FDA has not yet approved Cipla's DESCOVY ANDA, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Cipla's DESCOVY ANDA Product.

1103. Cipla's actions indicate that it does not intend to change its course of conduct.

1104. On information and belief, upon FDA approval of Cipla's DESCOVY ANDA, Cipla will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[56] by making, using, offering to sell, and/or selling Cipla's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1105. On information and belief, for example, Cipla's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1106. Cipla has actual knowledge of the '065 patent.

1107. On information and belief, Cipla became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

[56] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

1108. On information and belief, Cipla's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Cipla's DESCOVY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

1109. On information and belief, Cipla's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Cipla in the United States by it or on its behalf.

1110. On information and belief, Cipla's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Cipla's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent.

1111. On information and belief, physicians and healthcare providers will administer Cipla's DESCOVY ANDA Product in the United States according to the directions and instructions in Cipla's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

1112. On information and belief, at least through its Proposed DESCOVY Label, Cipla will encourage physicians and healthcare providers to administer Cipla's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent, and Cipla will know or should know that such conduct will occur.

1113. On information and belief, Cipla will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

1114. Through at least the foregoing actions, Cipla will actively induce the infringement of at least one claim of the '065 patent.

1115. On information and belief, Cipla knows or should know that Cipla's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '065 patent and that Cipla's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1116. The commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's DESCOVY ANDA Product will contribute to the actual infringement of the '065 patent.

1117. On information and belief, Cipla knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '065 patent.

1118. Through at least the foregoing actions, Cipla will contribute to the infringement of at least one claim of the '065 patent.

1119. On information and belief, if Cipla's DESCOVY ANDA is approved by the FDA, Cipla will make its DESCOVY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1120. On information and belief, Cipla's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Cipla's DESCOVY ANDA Product become a trivial and nonessential component of another product.

1121. Through at least the foregoing actions, Cipla will infringe at least one claim of the

'065 patent under 35 U.S.C. § 271(g).

1122. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product by Cipla prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

1123. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1124. Unless and until Cipla is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LVII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Cipla's DESCOVY ANDA Product

1125. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1126. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cipla has committed an act of infringement of the '769 patent by submitting Cipla's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product in the United States prior to the expiration of the '769 patent.

1127. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[57]

[57] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

1128. On information and belief, for example, Cipla's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1129. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1130. Unless and until Cipla is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LVIII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Cipla's DESCOVY ANDA Product

1131. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1132. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1133. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1134. Cipla has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Cipla's DESCOVY Notice Letter, Cipla intends to manufacture, use, offer for sale, sell, and/or import Cipla's DESCOVY ANDA Product within the United States.

1135. While the FDA has not yet approved Cipla's DESCOVY ANDA, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Cipla's DESCOVY ANDA Product.

1136. Cipla's actions indicate that it does not intend to change its course of conduct.

1137. On information and belief, upon FDA approval of Cipla's DESCOVY ANDA, Cipla will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[58] by making, using, offering to sell, and/or selling Cipla's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1138. On information and belief, for example, Cipla's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1139. Cipla has actual knowledge of the '769 patent.

1140. On information and belief, Cipla became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

1141. On information and belief, Cipla's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent.

[58] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

1142. On information and belief, Cipla's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Cipla in the United States by it or on its behalf.

1143. On information and belief, Cipla's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Cipla's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

1144. On information and belief, physicians and healthcare providers will administer Cipla's DESCOVY ANDA Product in the United States according to the directions and instructions in Cipla's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

1145. On information and belief, at least through its Proposed DESCOVY Label, Cipla will encourage physicians and healthcare providers to administer Cipla's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Cipla will know or should know that such conduct will occur.

1146. On information and belief, Cipla will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

1147. Through at least the foregoing actions, Cipla will actively induce the infringement of at least one claim of the '769 patent.

1148. On information and belief, Cipla knows or should know that Cipla's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that

Cipla's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1149. The commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

1150. On information and belief, Cipla knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

1151. Through at least the foregoing actions, Cipla will contribute to the infringement of at least one claim of the '769 patent.

1152. On information and belief, if Cipla's DESCOVY ANDA is approved by the FDA, Cipla will make its DESCOVY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1153. On information and belief, Cipla's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Cipla's DESCOVY ANDA Product become a trivial and nonessential component of another product.

1154. Through at least the foregoing actions, Cipla will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

1155. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product by Cipla prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

1156. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for

which damages are inadequate.

1157. Unless and until Cipla is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LIX: Infringement of the '791 Patent under 35 U.S.C. § 271(e)(2) by Cipla's DESCOVY ANDA Product

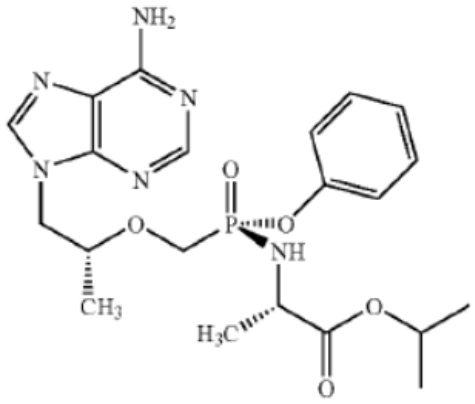
1158. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1159. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cipla has committed an act of infringement of the '791 patent by submitting Cipla's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product in the United States prior to the expiration of the '791 patent.

1160. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of the DESCOVY ANDA Product prior to the expiration of the '791 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[59]

1161. On information and belief, for example, Cipla's DESCOVY ANDA Product contains diastereomerically enriched compound, which can be represented by the following formula:

[59] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1162. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1163. Unless and until Cipla is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LX: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Cipla's DESCOVY ANDA Product

1164. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1165. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1166. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

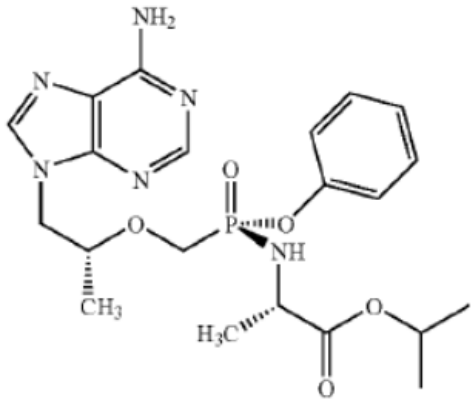
1167. Cipla has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Cipla's DESCOVY Notice Letter, Cipla intends to manufacture, use, offer for sale, sell, and/or import its DESCOVY ANDA Product within the United States.

1168. While the FDA has not yet approved Cipla's DESCOVY ANDA, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its DESCOVY ANDA Product.

1169. Cipla's actions indicate that it does not intend to change its course of conduct.

1170. On information and belief, upon FDA approval of Cipla's DESCOVY ANDA, Cipla will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[60] by making, using, offering to sell, and/or selling Cipla's DESCOVY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

1171. On information and belief, for example, Cipla's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1172. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for

[60] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

sale, sale, and/or importation of Cipla's DESCOVY ANDA Product by Cipla prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

1173. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1174. Unless and until Cipla is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXI: Infringement of the '788 Patent under 35 U.S.C. § 271(e)(2) by Cipla's DESCOVY ANDA Product

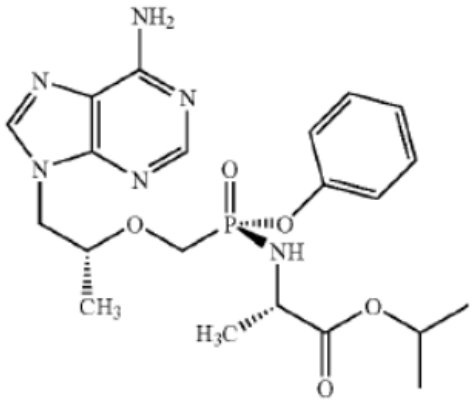
1175. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1176. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cipla has committed an act of infringement of the '788 patent by submitting Cipla's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product in the United States prior to the expiration of the '788 patent.

1177. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product prior to the expiration of the '788 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '788 patent, including but not limited to claim 7.[61]

1178. On information and belief, for example, Cipla's DESCOVY ANDA Product, in accordance with Cipla's Proposed DESCOVY Label, will be used in antiviral therapy comprising administering a therapeutically effective amount of a diastereomerically enriched compound, which can be represented by the following formula:

[61] Gilead will identify all asserted claims of the '788 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '788 patent, either literally or under the doctrine of equivalents.

1179. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1180. Unless and until Cipla is enjoined from infringing the '788 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXII: Declaratory Judgment of Infringement of the '788 Patent under 35 U.S.C. §§ 271(a)-(c) by Cipla's DESCOVY ANDA Product

1181. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1182. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1183. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

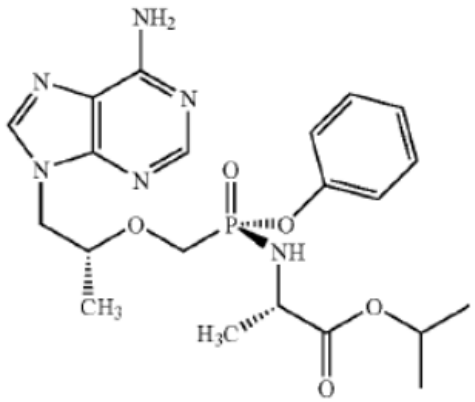
1184. Cipla has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Cipla's DESCOVY Notice Letter, Cipla intends to manufacture, use, offer for sale, sell, and/or import Cipla's DESCOVY ANDA Product within the United States.

1185. While the FDA has not yet approved Cipla's DESCOVY ANDA, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Cipla's DESCOVY ANDA Product.

1186. Cipla's actions indicate that it does not intend to change its course of conduct.

1187. On information and belief, upon FDA approval of Cipla's DESCOVY ANDA, Cipla will infringe one or more claims of the '788 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[62] by making, using, offering to sell, and/or selling Cipla's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '788 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

1188. On information and belief, for example, Cipla's DESCOVY ANDA Product, in accordance with Cipla's Proposed DESCOVY Label, will be used in antiviral therapy comprising administering a therapeutically effective amount of a diastereomerically enriched compound, which can be represented by the following formula:



[62] Gilead will identify all asserted claims of the '788 patent in accordance with this Court's Local Rules and/or scheduling order.

and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '788 patent, either literally or under the doctrine of equivalents.

1189. Cipla has actual knowledge of the '788 patent.

1190. On information and belief, Cipla became aware of the '788 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

1191. On information and belief, Cipla's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '788 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '788 patent. On information and belief, this knowledge is reflected through, among other things, Cipla's DESCOVY Notice Letter, which does not contest infringement of any claim of the '788 patent, except on the basis that those claims are allegedly invalid.

1192. On information and belief, Cipla's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Cipla in the United States by it or on its behalf.

1193. On information and belief, Cipla's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Cipla's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '788 patent.

1194. On information and belief, physicians and healthcare providers will administer Cipla's DESCOVY ANDA Product in the United States according to the directions and instructions in Cipla's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '788 patent.

1195. On information and belief, at least through its Proposed DESCOVY Label, Cipla will encourage physicians and healthcare providers to administer Cipla's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '788 patent, and Cipla will know or should know that such conduct will occur.

1196. On information and belief, Cipla will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '788 patent.

1197. Through at least the foregoing actions, Cipla will actively induce the infringement of at least one claim of the '788 patent.

1198. On information and belief, Cipla knows or should know that Cipla's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '788 patent and that Cipla's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1199. The commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's DESCOVY ANDA Product will contribute to the actual infringement of the '788 patent.

1200. On information and belief, Cipla knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '788 patent.

1201. Through at least the foregoing actions, Cipla will contribute to the infringement of at least one claim of the '788 patent.

1202. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Cipla's DESCOVY ANDA Product by Cipla prior to the expiration of the '788 patent will constitute direct infringement and/or will induce and/or

contribute to the actual and direct infringement of the '788 patent.

1203. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1204. Unless and until Cipla is enjoined from infringing the '788 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

ODEFSEY Counts

Count LXIII: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Cipla's ODEFSEY ANDA Product

1205. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1206. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cipla has committed an act of infringement of the '065 patent by submitting Cipla's ODEFSEY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product in the United States prior to the expiration of the '065 patent.

1207. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[63]

1208. On information and belief, for example, Cipla's ODEFSEY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1209. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's

[63] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1210. Unless and until Cipla is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXIV: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Cipla's ODEFSEY ANDA Product

1211. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1212. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1213. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1214. Cipla has submitted an ANDA for a generic version of Gilead's ODEFSEY pharmaceutical product. According to Cipla's ODEFSEY Notice Letter, Cipla intends to manufacture, use, offer for sale, sell, and/or import Cipla's ODEFSEY ANDA Product within the United States.

1215. While the FDA has not yet approved Cipla's ODEFSEY ANDA, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Cipla's ODEFSEY ANDA Product.

1216. Cipla's actions indicate that it does not intend to change its course of conduct.

1217. On information and belief, upon FDA approval of Cipla's ODEFSEY ANDA, Cipla will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[64] by making, using, offering to sell, and/or selling

[64] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

Cipla's ODEFSEY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1218. On information and belief, for example, Cipla's ODEFSEY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1219. Cipla has actual knowledge of the '065 patent.

1220. On information and belief, Cipla became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's ODEFSEY product.

1221. On information and belief, Cipla's efforts to make, use, sell, offer for sell, and/or import its ODEFSEY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Cipla's ODEFSEY Notice Letter, which does not contest infringement of at least claim 1 of the '065 patent, except on the basis that the claim is allegedly invalid.

1222. On information and belief, Cipla's ODEFSEY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Cipla in the United States by it or on its behalf.

1223. On information and belief, Cipla's Proposed ODEFSEY Label will include directions and instructions that instruct physicians and healthcare providers to administer Cipla's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the

methods described/claimed in the ’065 patent.

1224. On information and belief, physicians and healthcare providers will administer Cipla’s ODEFSEY ANDA Product in the United States according to the directions and instructions in Cipla’s Proposed ODEFSEY Label, and such administration will constitute direct infringement of at least one claim of the ’065 patent.

1225. On information and belief, at least through its Proposed ODEFSEY Label, Cipla will encourage physicians and healthcare providers to administer Cipla’s ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the ’065 patent, and Cipla will know or should know that such conduct will occur.

1226. On information and belief, Cipla will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the ’065 patent.

1227. Through at least the foregoing actions, Cipla will actively induce the infringement of at least one claim of the ’065 patent.

1228. On information and belief, Cipla knows or should know that Cipla’s ODEFSEY ANDA Product will be especially made or adapted for use in infringing the ’065 patent and that Cipla’s ODEFSEY ANDA Product is not suitable for substantial non-infringing use.

1229. The commercial manufacture, use, sale, offer for sale, and/or importation of Cipla’s ODEFSEY ANDA Product will contribute to the actual infringement of the ’065 patent.

1230. On information and belief, Cipla knows or should know that its offer for sale, sale and/or importation of its ODEFSEY ANDA Product will contribute to the actual infringement of the ’065 patent.

1231. Through at least the foregoing actions, Cipla will contribute to the infringement of at least one claim of the '065 patent.

1232. On information and belief, if Cipla's ODEFSEY ANDA is approved by the FDA, Cipla will make its ODEFSEY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1233. On information and belief, Cipla's ODEFSEY ANDA Product will not be materially changed by a subsequent process nor will Cipla's ODEFSEY ANDA Product become a trivial and nonessential component of another product.

1234. Through at least the foregoing actions, Cipla will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

1235. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product by Cipla prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

1236. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1237. Unless and until Cipla is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXV: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Cipla's ODEFSEY ANDA Product

1238. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1239. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cipla has committed an act of infringement of the '769 patent by submitting Cipla's ODEFSEY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product in the United States prior to the expiration of the '769 patent.

1240. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[65]

1241. On information and belief, for example, Cipla's ODEFSEY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1242. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1243. Unless and until Cipla is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXVI: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Cipla's ODEFSEY ANDA Product

1244. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1245. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[65] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

1246. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1247. Cipla has submitted an ANDA for a generic version of Gilead's ODEFSEY pharmaceutical product. According to Cipla's ODEFSEY Notice Letter, Cipla intends to manufacture, use, offer for sale, sell, and/or import Cipla's ODEFSEY ANDA Product within the United States.

1248. While the FDA has not yet approved Cipla's ODEFSEY ANDA, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Cipla's ODEFSEY ANDA Product.

1249. Cipla's actions indicate that it does not intend to change its course of conduct.

1250. On information and belief, upon FDA approval of Cipla's ODEFSEY ANDA, Cipla will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[66] by making, using, offering to sell, and/or selling Cipla's ODEFSEY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1251. On information and belief, for example, Cipla's ODEFSEY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls

[66] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1252. Cipla has actual knowledge of the '769 patent.

1253. On information and belief, Cipla became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's ODEFSEY product.

1254. On information and belief, Cipla's efforts to make, use, sell, offer for sell, and/or import its ODEFSEY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent.

1255. On information and belief, Cipla's ODEFSEY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Cipla in the United States by it or on its behalf.

1256. On information and belief, Cipla's Proposed ODEFSEY Label will include directions and instructions that instruct physicians and healthcare providers to administer Cipla's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

1257. On information and belief, physicians and healthcare providers will administer Cipla's ODEFSEY ANDA Product in the United States according to the directions and instructions in Cipla's Proposed ODEFSEY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

1258. On information and belief, at least through its Proposed ODEFSEY Label, Cipla will encourage physicians and healthcare providers to administer Cipla's ODEFSEY ANDA

Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Cipla will know or should know that such conduct will occur.

1259. On information and belief, Cipla will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

1260. Through at least the foregoing actions, Cipla will actively induce the infringement of at least one claim of the '769 patent.

1261. On information and belief, Cipla knows or should know that Cipla's ODEFSEY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Cipla's ODEFSEY ANDA Product is not suitable for substantial non-infringing use.

1262. The commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ODEFSEY ANDA Product will contribute to the actual infringement of the '769 patent.

1263. On information and belief, Cipla knows or should know that its offer for sale, sale and/or importation of its ODEFSEY ANDA Product will contribute to the actual infringement of the '769 patent.

1264. Through at least the foregoing actions, Cipla will contribute to the infringement of at least one claim of the '769 patent.

1265. On information and belief, if Cipla's ODEFSEY ANDA is approved by the FDA, Cipla will make its ODEFSEY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1266. On information and belief, Cipla's ODEFSEY ANDA Product will not be

materially changed by a subsequent process nor will Cipla's ODEFSEY ANDA Product become a trivial and nonessential component of another product.

1267. Through at least the foregoing actions, Cipla will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

1268. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product by Cipla prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

1269. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1270. Unless and until Cipla is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXVII: Infringement of the '791 Patent under 35 U.S.C. § 271(e)(2) by Cipla's ODEFSEY ANDA Product

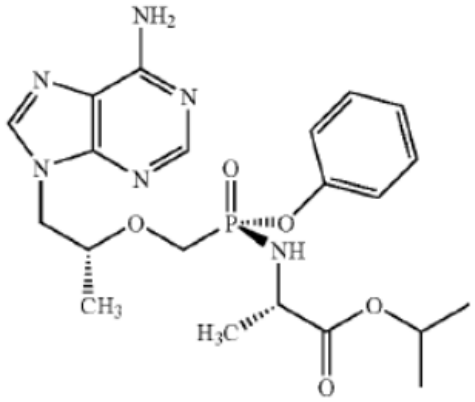
1271. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1272. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cipla has committed an act of infringement with respect to the '791 patent by submitting Cipla's ODEFSEY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product in the United States prior to the expiration of the '791 patent.

1273. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of the ODEFSEY ANDA Product prior to the expiration of the '791 patent, and its inducement of

and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[67]

1274. On information and belief, for example, Cipla's ODEFSEY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1275. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1276. Unless and until Cipla is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXVIII: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Cipla's ODEFSEY ANDA Product

1277. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1278. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

[67] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

1279. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1280. Cipla has submitted an ANDA for a generic version of Gilead's ODEFSEY pharmaceutical product. According to Cipla's ODEFSEY Notice Letter, Cipla intends to manufacture, use, offer for sale, sell, and/or import its ODEFSEY ANDA Product within the United States.

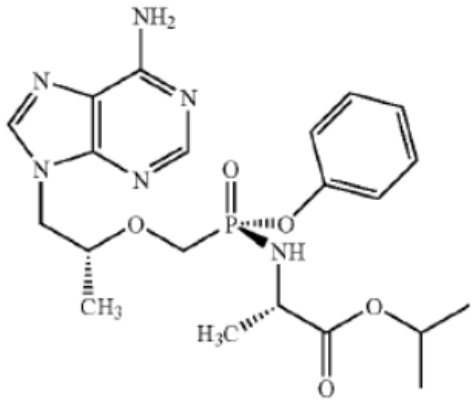
1281. While the FDA has not yet approved Cipla's ODEFSEY ANDA, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its ODEFSEY ANDA Product.

1282. Cipla's actions indicate that it does not intend to change its course of conduct.

1283. On information and belief, upon FDA approval of Cipla's ODEFSEY ANDA, Cipla will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[68] by making, using, offering to sell, and/or selling Cipla's ODEFSEY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

1284. On information and belief, for example, Cipla's ODEFSEY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:

[68] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1285. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product by Cipla prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

1286. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1287. Unless and until Cipla is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

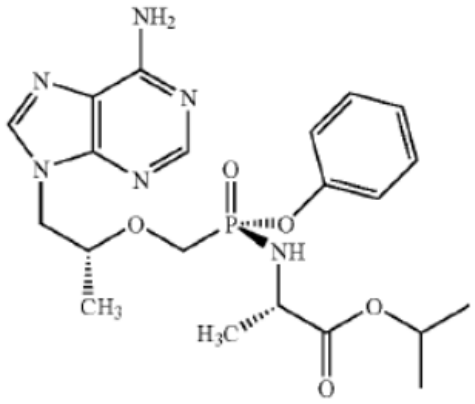
Count LXIX: Infringement of the '788 Patent under 35 U.S.C. § 271(e)(2) by Cipla's ODEFSEY ANDA Product

1288. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1289. Pursuant to 35 U.S.C. § 271(e)(2)(A), Cipla has committed an act of infringement with respect to the '788 patent by submitting Cipla's ODEFSEY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product in the United States prior to the expiration of the '788 patent.

1290. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product prior to the expiration of the '788 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '788 patent, including but not limited to claim 7.[69]

1291. On information and belief, for example, Cipla's ODEFSEY ANDA Product, in accordance with Cipla's Proposed ODEFSEY Label, will be used in antiviral therapy comprising administering a therapeutically effective amount of a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '788 patent, either literally or under the doctrine of equivalents.

1292. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1293. Unless and until Cipla is enjoined from infringing the '788 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

[69] Gilead will identify all asserted claims of the '788 patent in accordance with this Court's Local Rules and/or scheduling order.

Count LXX: Declaratory Judgment of Infringement of the '788 Patent under 35 U.S.C. §§ 271(a)-(c) by Cipla's ODEFSEY ANDA Product

1294. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1295. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1296. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1297. Cipla has submitted an ANDA for a generic version of Gilead's ODEFSEY pharmaceutical product. According to Cipla's ODEFSEY Notice Letter, Cipla intends to manufacture, use, offer for sale, sell, and/or import Cipla's ODEFSEY ANDA Product within the United States.

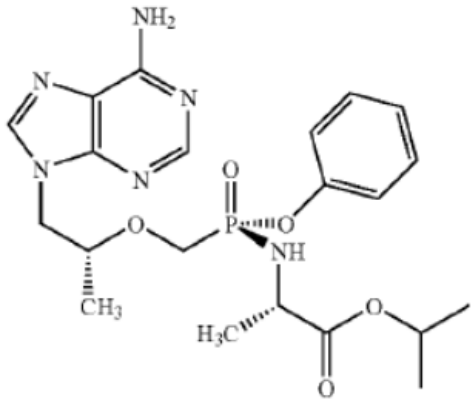
1298. While the FDA has not yet approved Cipla's ODEFSEY ANDA, Cipla has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Cipla's ODEFSEY ANDA Product.

1299. Cipla's actions indicate that it does not intend to change its course of conduct.

1300. On information and belief, upon FDA approval of Cipla's ODEFSEY ANDA, Cipla will infringe one or more claims of the '788 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[70] by making, using, offering to sell, and/or selling Cipla's ODEFSEY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '788 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

[70] Gilead will identify all asserted claims of the '788 patent in accordance with this Court's Local Rules and/or scheduling order.

1301. On information and belief, for example, Cipla's ODEFSEY ANDA Product, in accordance with Cipla's Proposed ODEFSEY Label, will be used in antiviral therapy comprising administering a therapeutically effective amount of a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '788 patent, either literally or under the doctrine of equivalents.

1302. Cipla has actual knowledge of the '788 patent.

1303. On information and belief, Cipla became aware of the '788 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's ODEFSEY product.

1304. On information and belief, Cipla's efforts to make, use, sell, offer for sell, and/or import its ODEFSEY ANDA Product have been made and will be made with full knowledge of the '788 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '788 patent. On information and belief, this knowledge is reflected through, among other things, Cipla's ODEFSEY Notice Letter, which does not contest infringement of any claims of the '788 patent, except on the basis that those claims are allegedly invalid.

1305. On information and belief, Cipla's ODEFSEY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Cipla in the United States by it or on its behalf.

1306. On information and belief, Cipla's Proposed ODEFSEY Label will include directions and instructions that instruct physicians and healthcare providers to administer Cipla's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '788 patent.

1307. On information and belief, physicians and healthcare providers will administer Cipla's ODEFSEY ANDA Product in the United States according to the directions and instructions in Cipla's Proposed ODEFSEY Label, and such administration will constitute direct infringement of at least one claim of the '788 patent.

1308. On information and belief, at least through its Proposed ODEFSEY Label, Cipla will encourage physicians and healthcare providers to administer Cipla's ODEFSEY ANDA Product in order to treat, *inter alia*, HIV-1 infection in accordance with the methods described/claimed in the '788 patent, and Cipla will know or should know that such conduct will occur.

1309. On information and belief, Cipla will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '788 patent.

1310. Through at least the foregoing actions, Cipla will actively induce the infringement at least one claim of the '788 patent.

1311. On information and belief, Cipla knows or should know that Cipla's ODEFSEY ANDA Product will be especially made or adapted for use in infringing the '788 patent and that

Cipla's ODEFSEY ANDA Product is not suitable for substantial non-infringing use.

1312. The commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ODEFSEY ANDA Product will contribute to the actual infringement of the '788 patent.

1313. On information and belief, Cipla knows or should know that its offer for sale, sale and/or importation of its ODEFSEY ANDA Product will contribute to the actual infringement of the '788 patent.

1314. Through at least the foregoing actions, Cipla will contribute to the infringement of at least one claim of the '788 patent.

1315. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Cipla's ODEFSEY ANDA Product by Cipla prior to the expiration of the '788 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '788 patent.

1316. The commercial manufacture, importation, use, sale, or offer for sale of Cipla's ODEFSEY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1317. Unless and until Cipla is enjoined from infringing the '788 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNTS LXXI-LXXIV AGAINST MACLEODS

DESCOVY Counts

Count LXXI: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Macleods's DESCOVY ANDA Product

1318. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1319. Pursuant to 35 U.S.C. § 271(e)(2)(A), Macleods has committed an act of infringement of the '065 patent by submitting Macleods's DESCOVY ANDA to obtain approval

to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's DESCOVY ANDA Product in the United States prior to the expiration of the '065 patent.

1320. Macleods's commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's DESCOVY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[71]

1321. On information and belief, for example, Macleods's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1322. The commercial manufacture, importation, use, sale, or offer for sale of Macleods's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1323. Unless and until Macleods is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXII: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Macleods's DESCOVY ANDA Product

1324. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1325. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1326. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

[71] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

1327. Macleods has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Macleods's DESCOVY Notice Letter, Macleods intends to manufacture, use, offer for sale, sell, and/or import Macleods's DESCOVY ANDA Product within the United States.

1328. While the FDA has not yet approved Macleods's DESCOVY ANDA, Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Macleods's DESCOVY ANDA Product.

1329. Macleods's actions indicate that it does not intend to change its course of conduct.

1330. On information and belief, upon FDA approval of Macleods's DESCOVY ANDA, Macleods will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[72] by making, using, offering to sell, and/or selling Macleods's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1331. On information and belief, for example, Macleods's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1332. Macleods has actual knowledge of the '065 patent.

1333. On information and belief, Macleods became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

[72] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

1334. On information and belief, Macleods's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent.

1335. On information and belief, Macleods's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Macleods in the United States by it or on its behalf.

1336. On information and belief, Macleods's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Macleods's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent.

1337. On information and belief, physicians and healthcare providers will administer Macleods's DESCOVY ANDA Product in the United States according to the directions and instructions in Macleods's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

1338. On information and belief, at least through its Proposed DESCOVY Label, Macleods will encourage physicians and healthcare providers to administer Macleods's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent, and Macleods will know or should know that such conduct will occur.

1339. On information and belief, Macleods will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

1340. Through at least the foregoing actions, Macleods will actively induce the infringement of at least one claim of the ’065 patent.

1341. On information and belief, Macleods knows or should know that Macleods’s DESCOVY ANDA Product will be especially made or adapted for use in infringing the ’065 patent and that Macleods’s DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1342. The commercial manufacture, use, sale, offer for sale, and/or importation of Macleods’s DESCOVY ANDA Product will contribute to the actual infringement of the ’065 patent.

1343. On information and belief, Macleods knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the ’065 patent.

1344. Through at least the foregoing actions, Macleods will contribute to the infringement of at least one claim of the ’065 patent.

1345. On information and belief, if Macleods’s DESCOVY ANDA is approved by the FDA, Macleods will make its DESCOVY ANDA Product using a process covered by one or more claims of the ’065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1346. On information and belief, Macleods’s DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Macleods’s DESCOVY ANDA Product become a trivial and nonessential component of another product.

1347. Through at least the foregoing actions, Macleods will infringe at least one claim of the ’065 patent under 35 U.S.C. § 271(g).

1348. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Macleods's DESCOVY ANDA Product by Macleods prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

1349. The commercial manufacture, importation, use, sale, or offer for sale of Macleods's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1350. Unless and until Macleods is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXIII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Macleods's DESCOVY ANDA Product

1351. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1352. Pursuant to 35 U.S.C. § 271(e)(2)(A), Macleods has committed an act of infringement of the '769 patent by submitting Macleods's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's DESCOVY ANDA Product in the United States prior to the expiration of the '769 patent.

1353. Macleods's commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's DESCOVY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[73]

[73] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

1354. On information and belief, for example, Macleods's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1355. The commercial manufacture, importation, use, sale, or offer for sale of Macleods's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1356. Unless and until Macleods is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXIV: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Macleods's DESCOVY ANDA Product

1357. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1358. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1359. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1360. Macleods has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Macleods's DESCOVY Notice Letter, Macleods intends to manufacture, use, offer for sale, sell, and/or import Macleods's DESCOVY ANDA Product within the United States.

1361. While the FDA has not yet approved Macleods's DESCOVY ANDA, Macleods has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Macleods's DESCOVY ANDA Product.

1362. Macleods's actions indicate that it does not intend to change its course of conduct.

1363. On information and belief, upon FDA approval of Macleods's DESCOVY ANDA, Macleods will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[74] by making, using, offering to sell, and/or selling Macleods's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1364. On information and belief, for example, Macleods's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1365. Macleods has actual knowledge of the '769 patent.

1366. On information and belief, Macleods became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

1367. On information and belief, Macleods's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent.

[74] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

1368. On information and belief, Macleods's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Macleods in the United States by it or on its behalf.

1369. On information and belief, Macleods's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Macleods's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 in accordance with the methods described/claimed in the '769 patent.

1370. On information and belief, physicians and healthcare providers will administer Macleods's DESCOVY ANDA Product in the United States according to the directions and instructions in Macleods's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

1371. On information and belief, at least through its Proposed DESCOVY Label, Macleods will encourage physicians and healthcare providers to administer Macleods's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Macleods will know or should know that such conduct will occur.

1372. On information and belief, Macleods will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

1373. Through at least the foregoing actions by Macleods will constitute active inducement of the infringement of the '769 patent.

1374. On information and belief, Macleods knows or should know that Macleods's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '769 patent

and that Macleods's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1375. The commercial manufacture, use, sale, offer for sale, and/or importation of Macleods's DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

1376. On information and belief, Macleods knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

1377. Through at least the foregoing actions, Macleods will contribute to the infringement of at least one claim of the '769 patent.

1378. On information and belief, if Macleods's DESCOVY ANDA is approved by the FDA, Macleods will make its DESCOVY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1379. On information and belief, Macleods's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Macleods's DESCOVY ANDA Product become a trivial and nonessential component of another product.

1380. Through at least the foregoing actions, Macleods will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

1381. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Macleods's DESCOVY ANDA Product by Macleods prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

1382. The commercial manufacture, importation, use, sale, or offer for sale of Macleods's

DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1383. Unless and until Macleods is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNTS LXXV-LXXXVI AGAINST HETERO

VEMLIDY Counts

Count LXXV: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Hetero's VEMLIDY ANDA Product

1384. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1385. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hetero has committed an act of infringement of the '065 patent by submitting Hetero's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's VEMLIDY ANDA Product in the United States prior to the expiration of the '065 patent.

1386. Hetero's commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's VEMLIDY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[75]

1387. On information and belief, for example, Hetero's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

[75] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

1388. If Hetero's marketing and sale of Hetero's VEMLIDY ANDA Product prior to expiration of the '065 patent and all other relevant exclusivities is not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

1389. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1390. Unless and until Hetero is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXVI: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Hetero's VEMLIDY ANDA Product

1391. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1392. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1393. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1394. Hetero has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Hetero's First VEMLIDY Notice Letter, Hetero intends to manufacture, use, offer for sale, sell, and/or import Hetero's VEMLIDY ANDA Product within the United States.

1395. While the FDA has not yet approved Hetero's VEMLIDY ANDA, Hetero has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Hetero's VEMLIDY ANDA Product.

1396. Hetero's actions indicate that it does not intend to change its course of conduct.

1397. On information and belief, upon FDA approval of Hetero's VEMLIDY ANDA,

Hetero will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[76] by making, using, offering to sell, and/or selling Hetero's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1398. On information and belief, for example, Hetero's VEMLIDY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1399. Hetero has actual knowledge of the '065 patent.

1400. On information and belief, Hetero became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

1401. On information and belief, Hetero's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Hetero's First VEMLIDY Notice Letter, which does not contest infringement of any claim of the '065 patent, except on the basis that those claims are allegedly invalid.

[76] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

1402. On information and belief, Hetero's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Hetero in the United States by it or on its behalf.

1403. On information and belief, Hetero's Proposed VEMLIDY Label will include directions and instructions that instruct physicians and healthcare providers to administer Hetero's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent.

1404. On information and belief, physicians and healthcare providers will administer Hetero's VEMLIDY ANDA Product in the United States according to the directions and instructions in Hetero's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

1405. On information and belief, at least through its Proposed VEMLIDY Label, Hetero will encourage physicians and healthcare providers to administer Hetero's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '065 patent, and Hetero will know or should know that such conduct will occur.

1406. On information and belief, Hetero will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

1407. Through at least the foregoing actions, Hetero will actively induce the infringement of at least one claim of the '065 patent.

1408. On information and belief, Hetero knows or should know that Hetero's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the '065 patent and that Hetero's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

1409. The commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's VEMLIDY ANDA Product will contribute to the actual infringement of the '065 patent.

1410. On information and belief, Hetero knows or should know that its offer for sale, sale and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the '065 patent.

1411. Through at least the foregoing actions, Hetero will contribute to the infringement of at least one claim of the '065 patent.

1412. On information and belief, if Hetero's VEMLIDY ANDA is approved by the FDA, Hetero will make its VEMLIDY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1413. On information and belief, Hetero's VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Hetero's VEMLIDY ANDA Product become a trivial and nonessential component of another product.

1414. Through at least the foregoing actions, Hetero will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

1415. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Hetero's VEMLIDY ANDA Product by Hetero prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

1416. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1417. Unless and until Hetero is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXVII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Hetero's VEMLIDY ANDA Product

1418. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1419. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hetero has committed an act of infringement of the '769 patent by submitting Hetero's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's VEMLIDY ANDA Product in the United States prior to the expiration of the '769 patent.

1420. Hetero's commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's VEMLIDY ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[77]

1421. On information and belief, for example, Hetero's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1422. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's

[77] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1423. Unless and until Hetero is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXVIII: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Hetero's VEMLIDY ANDA Product

1424. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1425. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1426. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1427. Hetero has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Hetero's First VEMLIDY Notice Letter, Hetero intends to manufacture, use, offer for sale, sell, and/or import Hetero's VEMLIDY ANDA Product within the United States.

1428. While the FDA has not yet approved Hetero's VEMLIDY ANDA, Hetero has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Hetero's VEMLIDY ANDA Product.

1429. Hetero's actions indicate that it does not intend to change its course of conduct.

1430. On information and belief, upon FDA approval of Hetero's VEMLIDY ANDA, Hetero will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[78] by making, using, offering to sell, and/or selling

[78] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

Hetero's VEMLIDY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1431. On information and belief, for example, Hetero's VEMLIDY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1432. Hetero has actual knowledge of the '769 patent.

1433. On information and belief, Hetero became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's VEMLIDY product.

1434. On information and belief, Hetero's efforts to make, use, sell, offer for sell, and/or import its VEMLIDY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Hetero's First VEMLIDY Notice Letter, which does not contest infringement of any claim of the '769 patent, except on the basis that those claims are allegedly invalid.

1435. On information and belief, Hetero's VEMLIDY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Hetero in the United States by it or on its behalf.

1436. On information and belief, Hetero's Proposed VEMLIDY Label will include

directions and instructions that instruct physicians and healthcare providers to administer Hetero's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent.

1437. On information and belief, physicians and healthcare providers will administer Hetero's VEMLIDY ANDA Product in the United States according to the directions and instructions in Hetero's Proposed VEMLIDY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

1438. On information and belief, at least through its Proposed VEMLIDY Label, Hetero will encourage physicians and healthcare providers to administer Hetero's VEMLIDY ANDA Product in order to treat, *inter alia*, hepatitis B infection in accordance with the methods described/claimed in the '769 patent, and Hetero will know or should know that such conduct will occur.

1439. On information and belief, Hetero will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

1440. Through at least the foregoing actions, Hetero will actively induce the infringement of at least one claim of the '769 patent.

1441. On information and belief, Hetero knows or should know that Hetero's VEMLIDY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Hetero's VEMLIDY ANDA Product is not suitable for substantial non-infringing use.

1442. The commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's VEMLIDY ANDA Product will contribute to the actual infringement of the '769 patent.

1443. On information and belief, Hetero knows or should know that its offer for sale, sale

and/or importation of its VEMLIDY ANDA Product will contribute to the actual infringement of the ’769 patent.

1444. Through at least the foregoing actions, Hetero will contribute to the infringement of at least one claim of the ’769 patent.

1445. On information and belief, if Hetero’s VEMLIDY ANDA is approved by the FDA, Hetero will make its VEMLIDY ANDA Product using a process covered by one or more claims of the ’769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1446. On information and belief, Hetero’s VEMLIDY ANDA Product will not be materially changed by a subsequent process nor will Hetero’s VEMLIDY ANDA Product become a trivial and nonessential component of another product.

1447. Through at least the foregoing actions, Hetero will infringe at least one claim of the ’769 patent under 35 U.S.C. § 271(g).

1448. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Hetero’s VEMLIDY ANDA Product by Hetero prior to the expiration of the ’769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’769 patent.

1449. The commercial manufacture, importation, use, sale, or offer for sale of Hetero’s VEMLIDY ANDA Product in violation of Gilead’s patent rights will cause harm to Gilead for which damages are inadequate.

1450. Unless and until Hetero is enjoined from infringing the ’769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

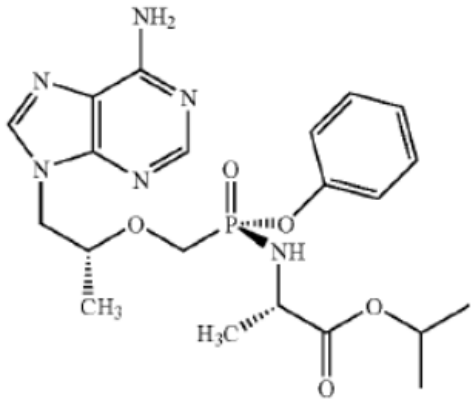
Count LXXIX: Infringement of the '791 Patent under 35 U.S.C. § 271(e)(2) by Hetero's VEMLIDY ANDA Product

1451. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1452. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hetero has committed an act of infringement of the '791 patent by submitting Hetero's VEMLIDY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's VEMLIDY ANDA Product in the United States prior to the expiration of the '791 patent.

1453. Hetero's commercial manufacture, use, offer for sale, sale, and/or importation of the VEMLIDY ANDA Product prior to the expiration of the '791 patent would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[79]

1454. On information and belief, for example, Hetero's VEMLIDY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1455. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's

[79] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1456. Unless and until Hetero is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXX: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Hetero's VEMLIDY ANDA Product

1457. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1458. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1459. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1460. Hetero has submitted an ANDA for a generic version of Gilead's VEMLIDY pharmaceutical product. According to Hetero's Second VEMLIDY Notice Letter, Hetero intends to manufacture, use, offer for sale, sell, and/or import its VEMLIDY ANDA Product within the United States.

1461. While the FDA has not yet approved Hetero's VEMLIDY ANDA, Hetero has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its VEMLIDY ANDA Product.

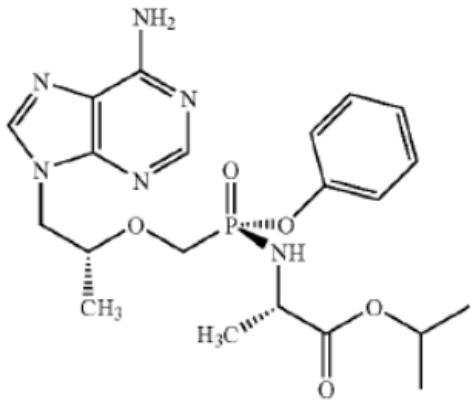
1462. Hetero's actions indicate that it does not intend to change its course of conduct.

1463. On information and belief, upon FDA approval of Hetero's VEMLIDY ANDA, Hetero will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[80] by making, using, offering to sell, and/or selling

[80] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

Hetero's VEMLIDY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

1464. On information and belief, for example, Hetero's VEMLIDY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1465. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Hetero's VEMLIDY ANDA Product by Hetero prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

1466. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's VEMLIDY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1467. Unless and until Hetero is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

DESCOVY Counts

Count LXXXI: Infringement of the '065 Patent under 35 U.S.C. § 271(e)(2) by Hetero's DESCOVY ANDA Product

1468. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1469. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hetero has committed an act of infringement of the '065 patent by submitting Hetero's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's DESCOVY ANDA Product in the United States prior to the expiration of the '065 patent.

1470. Hetero's commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's DESCOVY ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent, including but not limited to claim 1.[81]

1471. On information and belief, for example, Hetero's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

1472. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1473. Unless and until Hetero is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXXII: Declaratory Judgment of Infringement of the '065 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Hetero's DESCOVY ANDA Product

1474. Gilead realleges the foregoing paragraphs as if fully set forth herein.

[81] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

1475. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1476. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1477. Hetero has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Hetero's First DESCOVY Notice Letter, Hetero intends to manufacture, use, offer for sale, sell, and/or import Hetero's DESCOVY ANDA Product within the United States.

1478. While the FDA has not yet approved Hetero's DESCOVY ANDA, Hetero has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Hetero's DESCOVY ANDA Product.

1479. Hetero's actions indicate that it does not intend to change its course of conduct.

1480. On information and belief, upon FDA approval of Hetero's DESCOVY ANDA, Hetero will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[82] by making, using, offering to sell, and/or selling Hetero's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '065 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1481. On information and belief, for example, Hetero's DESCOVY ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

[82] Gilead will identify all asserted claims of the '065 patent in accordance with this Court's Local Rules and/or scheduling order.

1482. Hetero has actual knowledge of the '065 patent.

1483. On information and belief, Hetero became aware of the '065 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

1484. On information and belief, Hetero's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '065 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '065 patent. On information and belief, this knowledge is reflected through, among other things, Hetero's First DESCOVY Notice Letter, which does not contest infringement of any claim of the '065 patent, except on the basis that those claims are allegedly invalid.

1485. On information and belief, Hetero's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Hetero in the United States by it or on its behalf.

1486. On information and belief, Hetero's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Hetero's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent.

1487. On information and belief, physicians and healthcare providers will administer Hetero's DESCOVY ANDA Product in the United States according to the directions and instructions in Hetero's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '065 patent.

1488. On information and belief, at least through its Proposed DESCOVY Label, Hetero

will encourage physicians and healthcare providers to administer Hetero's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '065 patent, and Hetero will know or should know that such conduct will occur.

1489. On information and belief, Hetero will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '065 patent.

1490. Through at least the foregoing actions, Hetero will actively induce the infringement of at least one claim of the '065 patent.

1491. On information and belief, Hetero knows or should know that Hetero's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '065 patent and that Hetero's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1492. The commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's DESCOVY ANDA Product will contribute to the actual infringement of the '065 patent.

1493. On information and belief, Hetero knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '065 patent.

1494. Through at least the foregoing actions, Hetero will contribute to the infringement of at least one claim of the '065 patent.

1495. On information and belief, if Hetero's DESCOVY ANDA is approved by the FDA, Hetero will make its DESCOVY ANDA Product using a process covered by one or more claims of the '065 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1496. On information and belief, Hetero's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Hetero's DESCOVY ANDA Product become a trivial and nonessential component of another product.

1497. Through at least the foregoing actions, Hetero will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

1498. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Hetero's DESCOVY ANDA Product by Hetero prior to the expiration of the '065 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '065 patent.

1499. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1500. Unless and until Hetero is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXXIII: Infringement of the '769 Patent under 35 U.S.C. § 271(e)(2) by Hetero's DESCOVY ANDA Product

1501. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1502. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hetero has committed an act of infringement of the '769 patent by submitting Hetero's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's DESCOVY ANDA Product in the United States prior to the expiration of the '769 patent.

1503. Hetero's commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's DESCOVY ANDA Product prior to the expiration of the '769 patent, and its

inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent, including but not limited to claim 1.[83]

1504. On information and belief, for example, Hetero's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1505. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1506. Unless and until Hetero is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXXIV: Declaratory Judgment of Infringement of the '769 Patent under 35 U.S.C. §§ 271(a)-(c), (g) by Hetero's DESCOVY ANDA Product

1507. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1508. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1509. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1510. Hetero has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Hetero's First DESCOVY Notice Letter, Hetero intends to

[83] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

manufacture, use, offer for sale, sell, and/or import Hetero's DESCOVY ANDA Product within the United States.

1511. While the FDA has not yet approved Hetero's DESCOVY ANDA, Hetero has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Hetero's DESCOVY ANDA Product.

1512. Hetero's actions indicate that it does not intend to change its course of conduct.

1513. On information and belief, upon FDA approval of Hetero's DESCOVY ANDA, Hetero will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[84] by making, using, offering to sell, and/or selling Hetero's DESCOVY ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '769 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

1514. On information and belief, for example, Hetero's DESCOVY ANDA Product contains a composition comprising tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

1515. Hetero has actual knowledge of the '769 patent.

1516. On information and belief, Hetero became aware of the '769 patent no later than the date on which that patent was issued by the Patent Office and/or listed in the Orange Book for Gilead's DESCOVY product.

[84] Gilead will identify all asserted claims of the '769 patent in accordance with this Court's Local Rules and/or scheduling order.

1517. On information and belief, Hetero's efforts to make, use, sell, offer for sell, and/or import its DESCOVY ANDA Product have been made and will be made with full knowledge of the '769 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '769 patent. On information and belief, this knowledge is reflected through, among other things, Hetero's First DESCOVY Notice Letter, which does not contest infringement of any claim of the '769 patent, except on the basis that those claims are allegedly invalid.

1518. On information and belief, Hetero's DESCOVY ANDA Product, if FDA-approved, will be commercially manufactured, used, imported, offered for sale, and/or sold by Hetero in the United States by it or on its behalf.

1519. On information and belief, Hetero's Proposed DESCOVY Label will include directions and instructions that instruct physicians and healthcare providers to administer Hetero's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent.

1520. On information and belief, physicians and healthcare providers will administer Hetero's DESCOVY ANDA Product in the United States according to the directions and instructions in Hetero's Proposed DESCOVY Label, and such administration will constitute direct infringement of at least one claim of the '769 patent.

1521. On information and belief, at least through its Proposed DESCOVY Label, Hetero will encourage physicians and healthcare providers to administer Hetero's DESCOVY ANDA Product for, *inter alia*, the treatment of HIV-1 infection in accordance with the methods described/claimed in the '769 patent, and Hetero will know or should know that such conduct will occur.

1522. On information and belief, Hetero will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringe the '769 patent.

1523. Through at least the foregoing actions, Hetero will actively induce the infringement of at least one claim of the '769 patent.

1524. On information and belief, Hetero knows or should know that Hetero's DESCOVY ANDA Product will be especially made or adapted for use in infringing the '769 patent and that Hetero's DESCOVY ANDA Product is not suitable for substantial non-infringing use.

1525. The commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

1526. On information and belief, Hetero knows or should know that its offer for sale, sale and/or importation of its DESCOVY ANDA Product will contribute to the actual infringement of the '769 patent.

1527. Through at least the foregoing actions, Hetero will contribute to the infringement of at least one claim of the '769 patent.

1528. On information and belief, if Hetero's DESCOVY ANDA is approved by the FDA, Hetero will make its DESCOVY ANDA Product using a process covered by one or more claims of the '769 patent and import that product into the United States and/or offer to sell, sell or use that product in the United States.

1529. On information and belief, Hetero's DESCOVY ANDA Product will not be materially changed by a subsequent process nor will Hetero's DESCOVY ANDA Product become a trivial and nonessential component of another product.

1530. Through at least the foregoing actions, Hetero will infringe at least one claim of

the '769 patent under 35 U.S.C. § 271(g).

1531. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Hetero's DESCOVY ANDA Product by Hetero prior to the expiration of the '769 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '769 patent.

1532. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1533. Unless and until Hetero is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXXV: Infringement of the '791 Patent under 35 U.S.C. § 271(e)(2) by Hetero's DESCOVY ANDA Product

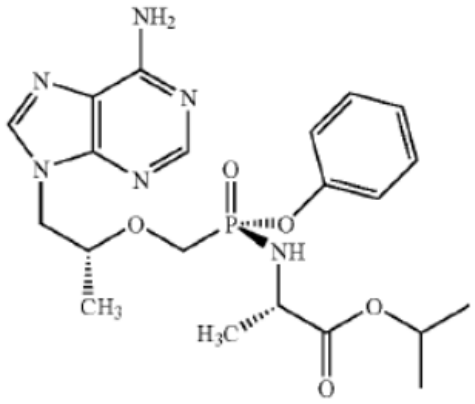
1534. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1535. Pursuant to 35 U.S.C. § 271(e)(2)(A), Hetero has committed an act of infringement of the '791 patent by submitting Hetero's DESCOVY ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's DESCOVY ANDA Product in the United States prior to the expiration of the '791 patent.

1536. Hetero's commercial manufacture, use, offer for sale, sale, and/or importation of the DESCOVY ANDA Product prior to the expiration of the '791 patent would constitute infringement of at least one of the claims of the '791 patent, including but not limited to claim 7.[85]

[85] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.

1537. On information and belief, for example, Hetero's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1538. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1539. Unless and until Hetero is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count LXXXVI: Declaratory Judgment of Infringement of the '791 Patent under 35 U.S.C. § 271(a) by Hetero's DESCOVY ANDA Product

1540. Gilead realleges the foregoing paragraphs as if fully set forth herein.

1541. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1542. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

1543. Hetero has submitted an ANDA for a generic version of Gilead's DESCOVY pharmaceutical product. According to Hetero's Second DESCOVY Notice Letter, Hetero intends to manufacture, use, offer for sale, sell, and/or import its DESCOVY ANDA Product within the United States.

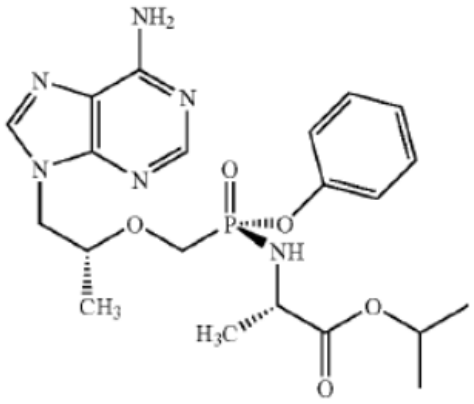
1544. While the FDA has not yet approved Hetero's DESCOVY ANDA, Hetero has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import its DESCOVY ANDA Product.

1545. Hetero's actions indicate that it does not intend to change its course of conduct.

1546. On information and belief, upon FDA approval of Hetero's DESCOVY ANDA, Hetero will infringe one or more claims of the '791 patent, either literally or under the doctrine of equivalents, including but not limited to claim 7,[86] by making, using, offering to sell, and/or selling Hetero's DESCOVY ANDA Product in the United States and/or importing said product into the United States under 35 U.S.C. § 271(a), unless enjoined by the Court.

1547. On information and belief, for example, Hetero's DESCOVY ANDA Product contains a diastereomerically enriched compound, which can be represented by the following formula:

[86] Gilead will identify all asserted claims of the '791 patent in accordance with this Court's Local Rules and/or scheduling order.



and/or its salts, tautomers, free base and solvates, and thus falls within the scope of at least claim 7 of the '791 patent, either literally or under the doctrine of equivalents.

1548. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of Hetero's DESCOVY ANDA Product by Hetero prior to the expiration of the '791 patent will constitute direct infringement of the '791 patent.

1549. The commercial manufacture, importation, use, sale, or offer for sale of Hetero's DESCOVY ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

1550. Unless and until Hetero is enjoined from infringing the '791 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

EXCEPTIONAL CASE

1551. Defendants were aware of the Patents-In-Suit prior to filing of an ANDA for a generic version of Gilead's VEMLIDY, DESCOVY, and/or ODEFSEY, and sending Notice Letters to Gilead.

1552. The actions of Defendants render this an exceptional case under 35 U.S.C. § 285.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Gilead hereby demands a trial by jury of all issues that are or may become so triable.

PRAYER FOR RELIEF

WHEREFORE, Gilead prays that this Court grant the following relief:

A) A judgment that each Defendant has infringed the '065 patent, the '769 patent, the '791 patent, and/or the '788 patent by submitting its respective ANDA(s) under Section 505(j) of the FFDCA, and that the making, using, offering to sell, and/or selling within the United States, and/or importation into the United States of Defendants' VEMLIDY, DESCOVY, and/or ODEFSEY ANDA Products will constitute an infringement of the '065 patent, the '769 patent, the '791 patent, and/or the '788 patent;

B) A judgment entered declaring that the Patents-In-Suit have not been proven invalid or unenforceable;

C) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Defendants' VEMLIDY, DESCOVY, and/or ODEFSEY ANDAs shall be a date which is not earlier than the latest expiration date of the Patents-In-Suit as extended by any applicable periods of exclusivity to which Gilead is or will be entitled;

D) An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, and/or selling in the United States, and/or importing into the United States any of Defendants' VEMLIDY, DESCOVY, and/or ODEFSEY ANDA Products until after the latest expiration date

of the Patents-In-Suit, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled;

E) An order pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that Defendants' commercial manufacture, use, offer for sell, sale, and/or importation of Defendants' VEMLIDY, DESCOVY, and/or ODEFSEY ANDA Products in or into the United States prior to the expiration of the Patents-In-Suit (including such actions by their officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Defendants or acting on Defendants' behalf) will constitute infringement of the Patents-In-Suit under 35 U.S.C. §§ 271 (a), (b), (c), and/or (g) and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

F) Damages or other monetary relief under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(c), and/or 35 U.S.C. § 284, including costs, fees, pre- and post-judgment interest, to Gilead if Defendants engage in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of any of Defendants' VEMLIDY, DESCOVY, and/or ODEFSEY ANDA Products prior to the latest expiration date of the Patents-In-Suit, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled;

G) An order that this case is exceptional under 35 U.S.C. § 285, and that Gilead be awarded reasonable attorneys' fees and costs; and

H) Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: October 15, 2021

FISH & RICHARDSON P.C.

By: */s/ Grayson P. Sundermeir*

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